Improving diabetes care

Nurse-led lifestyle counselling in primary care

Voor mijn ouders

The studies presented in this thesis have been performed at the Scientific Institute for Quality of Healthcare (IQ healthcare). This institute is part of the Nijmegen Centre for Evidence Based Practice (NCEBP), one of the approved research institutes of the Radboud University Nijmegen Medical Centre.

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Renate Maria Elisabeth Jansink

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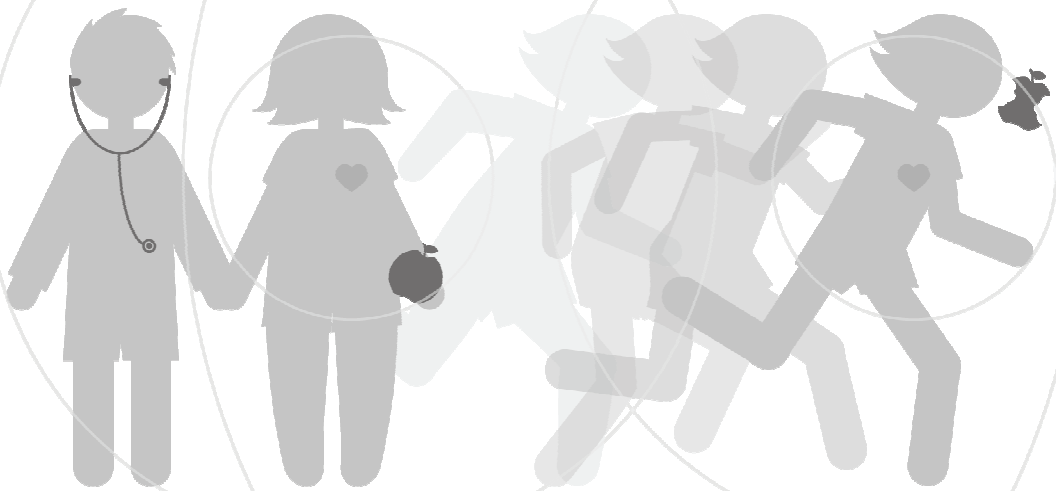
Promotoren:	Prof. dr. R.P.T.M. Grol
	Prof. dr. G. Elwyn (The Dartmouth Center for Health Care Delivery Science, US)
	Prof. dr. G.D.E.M. van der Weijden (Universiteit Maastricht)
Copromotor:	Dr. J.C.C. Braspenning
Manuscriptcommissie:	Prof. dr. W.J.J. Assendelft (voorzitter)
	Dr. L.D. Elving
	Prof. dr. N.K. de Vries (Universiteit Maastricht)

Contents

Chapter 1	General introduction	7
Chapter 2	Misperception of patients with type 2 diabetes about diet and physical activity, and its effects on readiness to change *Journal of Diabetes 2012; 4: 417–423.*	21
Chapter 3	Primary care nurses struggle with lifestyle counseling in diabetes care: a qualitative analysis *BMC Family Practice 2010; 11: 41.*	35
Chapter 4	Nurse-led motivational interviewing to change the lifestyle of patients with type 2 diabetes (MILD-project): protocol for a cluster, randomized, controlled trial on implementing lifestyle recommendations *BMC Health Services Research 2009; 9: 19.*	51
Chapter 5	No identifiable Hb1Ac or lifestyle change after a comprehensive diabetes programme including motivational interviewing: a cluster randomised trial *Scandinavian Journal of Primary Health Care 2013; 31: 119-127.*	77
Chapter 6	Minimal improvement of nurses' motivational interviewing skills in routine diabetes care one year after training: a cluster randomized trial *BMC Family Practice 2013; 14: 44.*	95
Chapter 7	General discussion	115
	Summary	133
	Samenvatting	139
	Dankwoord	145
	Curriculum Vitae	151

Chapter 1

General introduction



Diabetes mellitus is a major cause of morbidity and mortality worldwide. The incidence of type 2 diabetes increases, mainly due to ageing populations and changing lifestyles[1]. Patients with diabetes are at increased risk for cardiovascular diseases. Medication, a healthy diet and physical activity can reduce blood pressure, cholesterol, and the HbA1c, thereby lowering the risk of cardiovascular disease[2-5]. The health care professionals' adherence to the recommendations in diabetes guidelines on diagnosis and treatment of blood pressure, cholesterol and HbA1c is moderate[6,7]. This observation is linked to a lack of professionals' adherence to the type 2 diabetes recommendations on diet and physical activity[8-11]. Although lifestyle change is seen as a complex intervention that requests a patient-centred counselling-based approach[12,13], health care professionals pay relatively little attention to it during the consultation. Motivational interviewing (MI) is a method that seems to be effective in lifestyle changing[14-16]. In primary care the nurse can be educated in MI[17]; the involvement of the primary care nurse also improves the quality of diabetes care by structuring the care process. In this thesis a comprehensive structured diabetes programme focusing on lifestyle counselling was developed and evaluated to improve diabetes care.

To introduce the studies that have been performed in this thesis we describe the disease type 2 diabetes, its prevalence, the organization of diabetes care in the Netherlands, and people's misperceptions on their diet and physical activity. Furthermore, based on available evidence on effective diabetes care and effective lifestyle counselling, a prelude is given on potential successful elements of a comprehensive diabetes programme, to be tested in a randomized controlled trial. The introduction concludes by outlining the main research questions and the structure of this thesis.

Type 2 diabetes

Diabetes is a metabolic disease characterised by hyperglycaemia, caused by a lack of insulin secretion or insulin action. It affects approximately 285 million people worldwide and a prevalence of 439 million people with diabetes in the year 2030 has been predicted[18]. Type 1 diabetes accounts for approximately 10% of all diabetes cases and results from pancreatic beta-cell dysfunction, causing insulin deficiency, and leading to the requirement of exogenously administrated insulin for survival[19]. Type 2 diabetes is the most common type of diabetes,

accounting for approximately 90% of all cases[19]. Type 2 results from pancreatic beta-cells failing to compensate for insulin resistance through an increased secretion of insulin by beta-cells of the pancreas. Insulin resistance and beta-cell failure are both under the influence of genetic variation and other factors, such as dietary intake, physical activity, and obesity[18]. With increasing age the risk for developing type 2 diabetes also increases. Type 2 diabetes generally occurs after 40 years of age. The long term effects of type 2 diabetes include increased risk of complications such as foot ulcers, retinopathy, nephropathy, and neuropathy. Even more problematic is the fact that cardiovascular disease occurs at an earlier age in people with type 2 diabetes than in the general population. Moreover, over 50% of people suffering from diabetes die of cardiovascular disease[18]. Risk reduction strategies of diabetes mostly consist in lifestyle changing such as weight loss in obese people, increasing physical activity, dietary changes and smoking cessation, besides pharmacological treatment. People with type 2 diabetes occasionally need insulin when lifestyle changes and oral hypoglycaemic agents prove insufficient.

Diabetes care in the Netherlands

In the Netherlands, the estimated prevalence was 740,000 people with type 2 diabetes in 2007[19]. This prevalence is comparable to other EU-countries. Nowadays, care for people with type 2 diabetes is mainly provided in primary care (80%), and in many general practices diabetes care is increasingly delegated to primary care nurses[20,21]. These nurses are specialised in providing chronic care, such as for patients with diabetes. Their main tasks are to monitor clinical disease parameters and provide lifestyle advice. The majority of patients are seen quarterly by a primary care nurse and annually by their general practitioner, according to the current Dutch diabetes guidelines[20]. During the 3-monthly consultation, the nurse inquires after well-being, symptoms of hyper- or hypoglycaemia, complications concerning diet and physical activity, and the use of medication. Besides, the nurse assesses body weight and the fasting blood glucose value[20]. Once a year the consultation is more extensive. The primary care nurse or general practitioner inquires after vision and eyes, cardiovascular and sexual problems, discusses possible causes of these problems and options for treatment. This is followed by a physical examination (body weight, blood pressure, condition of the feet) with regard to chronic complications, and laboratory testing (fasting glucose, HbA1c,

creatinine concentration and clearance, lipids profile, albumin/creatinine ratio (or albumin concentration) in urine[20]. The most important parameter for glycaemic control is the percentage of glycosylated haemoglobin (HbA1c). The HbA1c-level is an estimate of the average plasma glucose concentration over a period of 6-8 weeks. Diabetes treatment is usually targeted at HbA1c-levels below 7%, depending on age, co-morbidity and life expectancy.
The Dutch guideline on diabetes mellitus from the Dutch College of General Practitioners recommends giving lifestyle advice on diet and physical activity, yet does not explain how the lifestyle counselling should be formatted and organised[20]. The introduction of the primary care nurse makes it possible to bring lifestyle counselling into the practice, because these nurses have been educated in lifestyle counselling. Lifestyle counselling includes a broad range of behaviour change strategies (e.g. decisional balance, goal setting, and self-monitoring) used by nurses when working collaboratively with patients[12]. However, despite the apparent advantages of this lifestyle counselling, the predominant focus in primary care is still on curative care, and the transition is taking place at a slow rate[12].

People's misperceptions on their diet and physical activity
The national diet and physical activity advices for the general population also apply to people with type 2 diabetes[22]. For fruit and vegetables the advice is to eat two pieces of fruit and 200 gram of vegetables per day[23-25]. As regards saturated fat intake, the maximum amount advised is 10% of the daily energy intake[25]. The national advice for exercise is at least 30 minutes of moderately intense activity, for at least five days a week[25,26]. It is known that the general population does not adhere optimally to the advices on diet and physical activity, and that most of them are unaware of their unhealthy lifestyle. As a result, they misperceive their own health-related behaviours[27-29]. People often regard their own lifestyle as more health promoting than it actually is. Studies showed that people frequently overestimated their fruit and vegetable consumption[28], as well as their physical activity[29], and underestimated their fat intake[30]. This misperception has adverse consequences for people's readiness to behavioural change[31]. People with misperceptions about their own behaviour do not pay attention to messages in health education interventions, because they think these messages do not apply to them. Misperception and its relation to readiness to change have mainly been researched among the general

population, but little is known about the misperceptions of people with type 2 diabetes.

Effective diabetes care

A Cochrane review[32] showed that high quality of care for patients with diabetes mellitus in primary care can improve patient and process outcomes. A multifaceted intervention is needed to achieve this. Promising elements of such an intervention are:

1) Structuring diabetes care. Elements of structured diabetes care are systematic follow-ups of patients with type 2 diabetes, treatment according to evidence-based diabetes guidelines, and insight into a social map for lifestyle support. The primary care nurse can play a supportive role in implementing these elements in diabetes care and maintaining the structured diabetes care.
2) Involving patients in the care given. Fundamental to a successful management of diabetes is the involvement of the patient with diabetes in his own care. The involvement makes the patient and professionals jointly responsible for deciding on a treatment and lifestyle change plan[33].
3) Reminders and feedback for professionals. These can be helpful in maintaining motivation, as well as getting feedback about professionals' performance[34]. A recent review by Boren et al.[35] indicated that diabetes care processes can be improved by providing reminders and feedback to nurses. Also, Renders et al.[32] showed that postgraduate education of health care professionals combined with local consensus procedures and/or reminders and/or audit and feedback improved the provision of diabetes care.

These elements of effective diabetes care can be applied to lifestyle counselling. Effective lifestyle counselling should include the following elements:

1) Lifestyle counselling should be implemented within structured diabetes care. Nurses can have an important role in lifestyle counselling, by playing a supportive role in defining specific goals and in making plans to achieve these goals[17]. While promoting behavioural change in a structured, co-operative and comprehensive way, they also see to it that practical barriers are overcome to facilitate the behavioural change of the patient[36].

However, we know that nurses perceive lifestyle counselling as a very demanding task[37]. Some studies suggest that nurses lack the skills to promote lifestyle changes[38-42].

2) Patients should become involved in lifestyle counselling. We assumed that the adherence to diet and exercise can be improved if lifestyle counselling is patient-centred. A promising patient-centred counselling technique is MI[4], even in brief encounters in general practice[14]. MI is formally defined as a client-centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence[17]. There are four general principles of MI: (1) express empathy, (2) develop discrepancies, (3) roll with resistance, and (4) support self-efficacy (see box 1). Five specific methods (open questions, affirming, reflecting, summarizing, and eliciting change talk) can be useful throughout the MI process. Some people consider techniques such as agenda setting, scaling questions, and determining importance and confidence as belonging to MI[43], yet others regard these as separate tools[44]. There is reasonable evidence that MI works in certain settings: it contributes to lifestyle change, such as reduced energy from fat, increased fruit and vegetable consumption[15], increased physical activity, decreased weight[16], resulting in beneficial effects on body mass index, cholesterol, and blood pressure[14].
3) Reminders and feedback for professionals should be introduced to maintain lifestyle counselling. Besides providing nurses with skills and knowledge to improve their performance in lifestyle counselling, they must be convinced of the importance of changing their practice and be motivated to carry it out. Reminders, such as an instruction chart with counselling techniques, and feedback to nurses about their own performance can be useful in maintaining lifestyle counselling.

In conclusion, a comprehensive programme heading for structured diabetes care, which is patient-centred with reminders and feedback for professionals, and with a clear role for lifestyle counselling has the potential to improve diabetes care. Yet no studies are known that tested all these elements in their implementation strategy to improve routine diabetes care.

Box 1. Description of motivational interviewing

Motivational Interviewing (MI) is formally defined as "a client centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence" (Miller and Rollnick, 2002). The MI approach is distinguished from some other counselling models; it is not focused on 'I will change you', but on 'If you wish, I can help you change'. The four guiding principles of MI are (1) express empathy, (2) develop discrepancies, (3) roll with resistance, and (4) support self-efficacy.

1) "Expressing empathy involves providing clients with an atmosphere of respect and acceptance of their position. The technique used is reflective listening and this is generally considered the foundation of MI and is recommended throughout the counselling process." Example script: 'Sounds like working on getting exercise and keeping up your blood glucose is very demanding. I think it is natural to struggle sometimes. What is it like for you? Are there any obstacles that make it particularly difficult?'
2) "Develop discrepancies involves creating a 'gap' between the client's current behaviour and their broader goals, thus cultivating motivation for lifestyle change. When the client recognizes such discrepancies, a certain level of discontent arises that makes change more likely to occur. Discrepancies are developed by exploring the client's important life values and reviewing how their current behaviours affect their ideal lifestyle". Example script: 'So on the one hand you are not sticking with your exercise program, because it's hard to find time but on the other hand you think exercise would make you feel better and help manage your blood glucose level. It sounds like managing diabetes is pretty important to you. How do you think having a high BMI affect this overall? Where do the exercises fit in here?'
3) "Directly challenging resistance is counterproductive to lifestyle change because it typically results in the client defending their current state of affairs. Rather, resistance should be rolled with and channelled instead of confronted. Rolling with resistance invites the client to consider a new perspective versus having it imposed". Example script: 'It can be very frustrating to make all these changes, especially when it has becoming a habit and others giving you hard time. I think it is completely normal to want to go back to old habits when times are tough. May I tell you about some different options that have been worked well for others?'
4) "Self-efficacy, or one's confidence in the ability to change a specific behaviour under difficult circumstances, should be supported whenever possible because it is one of the best predictors of treatment outcome. Self-efficacy can be strengthened by affirming past success (i.e., reinforcement), presenting success stories of others (i.e., modelling), and expressing their belief in the client's potential to change". Example script: 'I see you have been keeping up your blood glucose level despite the difficulties adhering to your diet and exercises. It looks like you had a lot of initial success when you began making health changes. What worked so well for you then? Sometimes a setback can actually be a good thing.'

Comprehensive diabetes programme

Compliance to lifestyle advice decreases when several lifestyle behaviours are targeted at the same time[45], such as for patients with type 2 diabetes. We need a comprehensive programme based on structuring diabetes care, involving patients in the care given, and reminders and feedback for professionals with specific attention to lifestyle counselling, based on these elements as well.

Therefore, we developed and evaluated a comprehensive diabetes programme with the following elements (see box 2):

- Training nurses in agenda setting for diabetes consultations, tailoring a protocol based on diabetes guidelines to the local setting, and introducing a social map for lifestyle support to make diabetes care more structured;
- A record keeping of consultation data and behavioural change of the patients to embed lifestyle counselling in usual care;
- Training primary care nurses in the principles of MI to involve patients in diabetes care;
- An instruction chart with counselling techniques, as a reminder for nurses to maintain the MI techniques. Regular telephone follow-ups for diabetes patients and a help desk function for nurses to inquire about their development of lifestyle counselling. Also, a follow-up meeting for nurses to receive feedback about their own video recording.

The comprehensive diabetes programme was built on elements that had been proven by others to be effective. An essential component of the programme was MI. Most of the research in the area examined the effect of MI on a single behaviour, whereas diabetes is a complex chronic illness that requires multiple behaviour change[46]. However, a review by Martins et al.[16] indicated that MI shows potential for diabetes care, but the interventions consisted of separate MI sessions aimed at behaviour change instead of MI embedded in usual care. Consistent evidence for the effectiveness of MI in diabetes care is still limited and additional research is indicated[38,47].

Box 2. The several interventions of the comprehensive diabetes programme

Training in motivational interviewing (4 half-days, spread equally over 6 months)

1. **Training** primary care nurses in the principles of **motivational interviewing (MI)** in order to encourage patients with diabetes to adhere to lifestyle guidelines. The following components were discussed:
   - *Building motivation for change: importance and confidence*
   - *Asking open questions, listening reflectively, affirming, summarizing, and eliciting change*
   - *Expressing empathy, developing discretion, rolling with resistance, and supporting self-efficacy.*

Structured diabetes care

2. Training in **agenda setting** to make consultations more structured and to draw up concrete appointments.
3. Tailoring a **diabetes protocol** to the local setting.
4. Introducing a **social map** for lifestyle change to primary care nurses. The map provides an overview of all available organizations and their treatment programmes to help patients choose, for example, the right sport school or physiotherapist.

Lifestyle counselling embedded in usual care

5. **Record keeping** of consultation data and changes in the behaviour of patients, conducted by primary care nurses.

Maintained motivational interviewing

Reminder

6. An **instruction chart** with counselling techniques, as a reminder for nurses to encourage maintenance of the MI techniques used to help patients change.

Follow-up

7. Recommendations for **regular telephone follow-ups** for diabetes patients, which are monthly in the first 6 months and then probably decrease.
8. A **help desk**: the research team will call the primary care nurse three times to inquire about their development of health counselling and nurses can call the research team for information.
9. A **follow-up meeting** to receive feedback about their own video recordings.

Not only the effect of the comprehensive programme on the patients' clinical parameters was studied, but also the effect of the training programme on the nurses' MI performance. Many studies measured the effect of MI on patients' behaviours, but few studies are available that looked into detail on the nurses' MI abilities before and after a training programme[38,16]. In two studies, training in MI seem to have a positive effect on MI skills of general practitioners[48] and nurses[49], but the researchers recommended to assess the level of MI use with video-taped consultations instead of self-reported data.

Research questions and thesis outline

In *chapter 2* a survey study is described in which the adherence to the national recommendation on diet and physical activity is described for people with type 2 diabetes as well as their misperception on these lifestyle behaviours and its relationship with readiness to change. This type of information was known for the general population, but not yet for people with type 2 diabetes.

> *Research question: How many people with type 2 diabetes misperceived their lifestyle behaviours on fruit, vegetable and fat consumption, as well as physical activity in comparison to the Dutch general population? To what extent is the misperception of people with type 2 diabetes related to readiness to change?*

Primary care nurses can help people with type 2 diabetes in becoming more aware of lifestyle behaviour. In fact, most lifestyle counselling starts with getting insight into actual behaviour. However, nurses find it difficult to practice lifestyle counselling. In-depth interviews were held in order to get a good overview of nurses' barriers in lifestyle counselling for people with type 2 diabetes. The results are described in *chapter 3* and were used to fine-tune the comprehensive diabetes programme.

> *Research question: Which lifestyle counselling barriers do nurses encounter at the nurse level, the patient level, and the practice level?*

The comprehensive diabetes programme has been developed and evaluated on its effect. In *chapter 4* we describe the study protocol of the randomized controlled trial (MILD study) and in *chapter 5* the results. Important patient outcome measurements have been defined, such as HbA1c, blood pressure and the cholesterol level as well as the information on their readiness to change diet and physical activity and quality of life. We also checked the exposure to the comprehensive diabetes programme.

> *Research question: What is the effect of a comprehensive diabetes programme on clinical parameters (HbA1c, blood pressure, cholesterol, and BMI), lifestyle (alcohol, fat, vegetables, fruit, and*

physical activity) as well as quality of life and patients' readiness to change lifestyle?

Regarding the nurses, we were especially interested in the extent to which they were able to apply the principle of MI. In a separate video study we compared nurses' skills on MI before and a year after our comprehensive diabetes programme had been implemented (chapter 6). The question we would like to answer was if the programme based on MI effectively prepared the nurses to practice MI in diabetes care.

Research question: What is the effect of a comprehensive diabetes programme on nurses' skills on MI in a controlled study?

Chapter 7 gives an overall general discussion on improving diabetes care while focusing on lifestyle counselling. Methodological considerations on the studies that have been carried out have been given as well as implications for further research and practice. This thesis concludes with a summary in English and Dutch.

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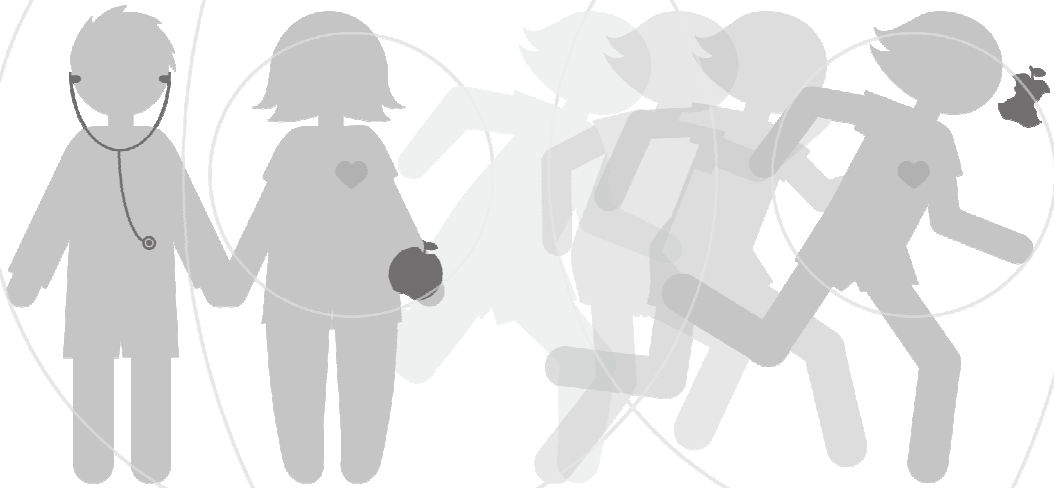
Chapter 2

Misperception of patients with type 2 diabetes about diet and physical activity, and its effects on readiness to change

Renate Jansink
Jozé Braspenning
Ellen Keizer
Trudy van der Weijden
Glyn Elwyn
Richard Grol



Journal of Diabetes 2012; 4: 417-423

Abstract

Background: The aim of the present study was to assess misperceptions about lifestyle among patients with type 2 diabetes and their effects on readiness to change.

Methods: Nine hundred and forty patients, with an HbA1c >7% and a body mass index >25 kg/m2, from 57 general practices participated in a cross-sectional survey. Misperceptions of lifestyle (fruit, vegetable, and fat consumption, as well as physical activity) and readiness to change were determined with validated questionnaires. Logistic regression analysis calculated the association of misperception with readiness to change.

Results: The response rate was 55.4%. Misperception existed for all lifestyle behaviors (physical activity, 41.5%; consumption of fruit, 40.1%; consumption of vegetables, 69.2%; consumption of fat, 21.6%). Misperception significantly affected readiness to change the relevant lifestyle (odds ratios [95% confidence intervals] ranging from 2.67 [1.68–4.23] to 1.80 [1.16–2.79]), except in the case of fruit consumption. The degree of misperception varied greatly between the different lifestyle behaviors and was somewhat larger (1–10%) than that in the general Dutch population.

Conclusions: Patients with type 2 diabetes misperceive their lifestyle behaviors, which hinders lifestyle changes. The variations in misperception and readiness to change show that diversity should be considered in lifestyle counseling for patients with type 2 diabetes.

Introduction

Lifestyle management is the key element in type 2 diabetes (T2D) care. A healthy diet and physical activity can lower blood pressure and reduce cholesterol and HbA1c concentrations[1,2]. In The Netherlands, the necessary lifestyle modifications challenge not only the patients themselves, but also the primary care nurses involved in delivering diabetes care in this country. Structured lifestyle programs can be facilitative; some have even been developed specifically for diabetes care and sometimes focus on certain age groups[3-5]. The success of these programs, which are based mainly on techniques to change behavior, has varied considerably[6-8]. A recent review indicates that a technique to promote patients' awareness of personal risk behavior was most likely to contribute to a successful behavioral change[9]. Prochaska and DiClemente found that awareness of personal risk behavior is particularly important to proceed from precontemplation to contemplating behavioral change in the stages-of-change concept[10]. Based on Weinstein's[11] precaution adoption model, the expectation is that patients only proceed to contemplation when they are aware that they personally engage in an unhealthy lifestyle. However, many patients are not aware of their unhealthy lifestyle: they misperceive their own health-related behaviors[12-14]. Patients often regard their own lifestyle as more health-promoting than it actually is. There is discordance between the patient's actual lifestyle and his/her perception of it[12]. Studies showed that people frequently overestimated their fruit and vegetable consumption[13], as well as their physical activity[14], and underestimated their fat intake[15]. These misperceptions may adversely affect patients' readiness to change[16]. Patients with misperceptions about their own behavior do not pay attention to messages in health education interventions because they think these messages do not apply to them.

Misperceptions and their relation to readiness to change have been investigated mainly in general populations[12,17]. It is unclear to what extent misperception applies to patients with specific chronic conditions, such as T2D. Awareness of the chronic condition can improve readiness to change health-related behaviors (Hypothesis 1)[18]. However, the multifaceted treatment regimen of T2D can track the awareness in which misperception becomes more obvious (Hypothesis 2)[19,20].

The aim of the present study was to assess how many patients with T2D misperceived their lifestyle behaviors concerning fruit, vegetable, and fat

consumption, as well as physical activity, and to compare the data with those for the general Dutch population. Furthermore, it considered the extent to which this misperception was related to readiness to change.

Methods

Study design and participants

In The Netherlands, T2D care is delivered mainly by primary care nurses working in general practices. Patients with T2D from these practices were included in the present study if they were <80 years of age and if their HbA1c was >7.0% and their body mass index (BMI) was >25 kg/m^2. The exclusion criteria were complex comorbidities (e.g. mental illness or end-stage cancer) and treatment in hospital. Two members of the research team made a list of all eligible patients in the participating practices by extracting data about age, HbA1c, and BMI from the medical files. Each patient eligible for inclusion in the study received a letter from the general practitioner inviting them to participate in the study, a lifestyle questionnaire, and an informed consent form. The patients were asked to respond by returning the signed informed consent form and the completed questionnaire to the research team. Non-respondents were received a reminder letter 4 weeks later[21]. The Medical Ethics Committee of the University of Nijmegen granted ethics approval for the study (16 January 2006; reference no. JvG/CMO 0116).

Lifestyle behaviors

Fruit, vegetables, and fat

We used two validated, self-administrated questionnaires to list the habitual intake of fruit, vegetables[22], and fat[23] with a reference period of 1 month. Patients were asked to state the frequency (daily or weekly) of their usual portion size for each category of fruit, vegetables, and fat in units such as serving spoons (50–60 g), pieces, or glasses.

In addition, the habitual intake of fruit, vegetables, and fat was compared with the national nutrition recommendations. The recommendations include two servings of fruit and 200 g vegetables per day, with the exclusion of high-carbohydrate vegetables, such as potatoes and corn[24-26]. The scores for fat consumption first had to be calculated in points instead of g fat (or the percentage of energy from fat)[23]. The total fat scores ranged from 0 to 80 points; the lower the score, the lower the fat intake. The upper levels of

recommended total fat consumption were fat scores of 15 points for women and 18 points for men[27]. By comparing habitual intake to national recommendations, it became clear as to whether each patient complied with the nutrition recommendations for fruit, vegetables, and fat (objective measurement of compliance).

Physical activity

Physical activity was measured using the validated Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire[28]. Patients were asked to describe the frequency of their activities (sports, daily work, etc.) for a typical week in the previous month. We determined the intensity of the activities using the coding scheme of Ainsworth et al.[29] On the basis of the frequency and intensity of physical activity, patients were classed in one of two activity categories, namely "moderate intensity" or "low intensity". We also evaluated physical activity using the general question, "How many days a week do you take part in moderately intense activities for at least 30 min?"

The national exercise recommendation is at least 30 min of moderately intense activity at least 5 days a week[24,30]. Patients were only considered to adhere to this recommendation if the answers to both the CHAMPS questionnaire and the general question confirmed the statement. The physical activity score was also expressed as an objective measurement of compliance to the recommendation.

Misperception

We defined "misperception" by comparing the patient's perception of each lifestyle behavior with the more objective measurements of compliance as described above[14,31]. The survey measured patients' perceptions on a five-point Likert scale. We defined "misperception" as a discrepancy between the patient's perception and the objective measurements. Patients whose objective measurements of compliance confirmed their lifestyle perceptions were referred to as realists.

Readiness to change

We added two questions to the survey for each lifestyle behavior to determine readiness to change. These items concerned the patients' beliefs about the importance of change and self-confidence in changing[32]. For example, the survey included the following questions: "How important is it for you to eat

more fruit?"; and "If you have decided to eat more fruit, how confident are you in succeeding?" Both answers were rated on a Likert scale ranging from "very unimportant" to "very important" (range 1–5) and from "not very much confidence" to "very much confidence" (range 1–5). Patients who were ready to change answered that a healthy lifestyle was important (minimum score 4) and that they felt confident about making lifestyle changes (minimum score 4). Patients who were unready to change their lifestyle thought it unimportant (score <4) and/or lacked confidence (score <4).

Statistical analysis

The demographics of the study population, diabetes characteristics, non-compliance and misperception of fat, fruit, and vegetable intake, as well as physical activity, were examined using descriptive statistics. Logistic regression analyses were used to determine the association between misperception and readiness to change for each lifestyle behavior separately. In this analysis, misperception was the independent variable and readiness to change was the dependent variable. Patients with misperception were compared with the realists. Furthermore, clustering of misperception of various lifestyles was determined with the Phi test[33]. All statistical analyses were performed using SPSS for Windows (SPSS, Chicago, IL, USA). $P<0.05$ was considered significant.

Results

Participant characteristics

Fifty-seven general practices and 940 patients with T2D participated in the present study. The response rate to the baseline questionnaire was 55.4% (521 / 940).

Table 1 gives an overview of the demographic characteristics of the patients, the characteristics of their diabetes, and information regarding non-compliance to lifestyle behaviors.

Table 1. Demographics of the study population

No. respondents to baseline questionnaire	521
Demographics	
Median (IQR) age (years)	65 (59–70)
% Men	54.8
% Living alone	23.5
% Low level of education (vocational training or less)	54.4
% Dutch ethnicity	91.5
Diabetes characteristics	
Median (IQR) duration of diabetes (years)	6 (3–10)
Median (IQR) HbA1c (%)	7.5 (7.2–8.0)
Median (IQR) BMI (kg/m^2)	29.8 (27.6–33.5)
Non-compliance of lifestyle behaviors (%)	
Fruit consumption (<2 servings/day)	55.4
Vegetable consumption (<200 g/day)	74.2
Fat consumption* (≥19 points for men; (≥16 points for women)	23.7
Physical activity#	51.2

*Total fat scores ranged from 0 to 80 points. The upper levels of recommended total fat consumption for men and women are fat scores of 18 and 15 points, respectively[27].
National exercise recommendations are at least 30 min moderately intense activity at least 5 days a week[24,30]. Non-compliance was deemed to occur in subjects who reported <30 min/day moderately intense exercise, 5 days a week.
IQR, interquartile range; BMI, body mass index.

Misperception and readiness to change

Patients' misperception varied among the different lifestyle behaviors: vegetable consumption, 69.2%; physical activity, 41.5%; fruit consumption, 40.1%; and fat consumption, 21.6%. These numbers are slightly higher than those for the general Dutch population (table 2).

Table 2. Misperception of fruit, vegetable, and fat consumption as well as physical activity, in the study and general Dutch populations

	Study population	General Dutch population
Misperception about		
Fruit consumption (%)	40.1	36[40] /40[22]
Vegetable consumption (%)	69.2	28[20] /68[22]
Fat consumption (%)	21.6	10[41]
Physical activity (%)	41.5	16[12,16] /36[14]

Data for the general Dutch population were obtained from previous studies, as indicated.

As indicated in table 3, the association between misperception and readiness to change one's lifestyle was significant for vegetables (odds ratio [OR] 1.80; 95% confidence interval [CI] 1.16–2.79; P=0.009; R2=0.02), fat (OR 2.67; 95% CI 1.68–4.23; P=0.000; R2=0.05), and physical activity (OR 1.92; 95% CI 1.24–2.96;

P=0.003; R2=0.03). Therefore, patients with T2D who accurately perceived their lifestyle behavior for vegetable consumption were 1.8-fold more ready to change their vegetable consumption than patients who misperceived their behavior about eating vegetables. Readiness to change their lifestyle behaviors was affected mainly by the patients' limited confidence in changing their behavior, with very little contribution of a patient's belief in its importance. Significant associations for misperception among different lifestyle behaviors were found only for fruit and fat consumption (u=0.11).

Table 3. Associations between misperception and unreadiness to change, considered unimportance of change and lack of confidence

	Lifestyle behavior			
	Fruit consumption	**Vegetable consumption**	**Fat consumption**	**Physical activity**
Unreadiness to change				
n	373	441	437	351
Misperception[#]				
OR (95% CI)	1.25 (0.84–1.88)	1.80*(1.16–2.79)	2.67*(1.68–4.23)	1.92*(1.24–2.96)
P-value	0.276	0.009	0.000	0.003
R^2	0.04	0.02	0.05	0.03
Patient perceive change as unimportant				
n	388	459	451	363
Misperception[#]				
OR (95% CI)	0.84 (0.56–1.25)	1.46 (0.94–2.27)	1.61 (0.99–2.60)	1.35 (0.88–2.07)
P-value	0.379	0.089	0.053	0.173
R^2	0.04	0.01	0.01	0.01
Patient lacks confidence to make change				
n	377	442	438	352
Misperception[#]				
OR (95% CI)	1.78* (1.13–2.80)	1.47 (0.88–2.46)	2.98* (1.88–4.72)	2.42* (1.57–3.73)
P-value	0.013	0.147	0.000	0.000
R^2	0.02	0.01	0.04	0.06

*P < 0.05.

[#] "Realists" (i.e. patients whose objective measurements of compliance confirmed their lifestyle perceptions) were used as the reference value (1.0).

OR, odds ratio; CI, confidence interval; *n*, number of respondents.

Discussion

Patients with T2D misperceive their health lifestyle behaviors, which hinders lifestyle changes. We have shown this misperception of lifestyle behaviors for fruit, vegetable, and fat consumption, as well as for physical activity, although the percentages differed considerably. The proportion of patients who misperceived their health lifestyle behaviors was slightly greater than that for the general Dutch population (confirmation of Hypothesis 2). The readiness to change was related to misperception of healthy lifestyle behaviors for vegetable and fat consumption, as well as for physical activity. Patients with T2D often had problems with more than one lifestyle behavior, but the present study shows that the misperceptions of the different lifestyle behaviors were not related, except for fruit and fat consumption. It is therefore possible for patients to accurately perceive one lifestyle behavior and to misperceive another.

The present study has some limitations. The actual number of diabetes patients with a misperception of their health lifestyle behavior may have been underestimated owing to the self-administrative nature of the survey. This could have led to socially desirable answers resulting in an overestimation of the number of realists with a healthy lifestyle. Even so, the questionnaires were validated instruments that are widely used for behavioral studies of lifestyle behaviors. Another weakness of the study is the relatively low response rate, although the rate is comparable to the response rates of similar Dutch studies[16,28] Perhaps non-respondents did not want to be confronted with their lifestyle behaviors, which may again contribute to an underestimation of the number of patients with a misperception.

The results of the present study confirmed the second hypothesis that patients with T2D are less aware of their actual lifestyle behaviors than the general population. Type 2 diabetes is a complex disorder that requires patients to pay attention to various aspects of their lifestyle, including weight, blood pressure, glucose monitoring, and medication[19]. Adherence to this multifaceted treatment regimen is a challenge, with patients more likely to adhere to their medication regimens than to work on nutrition and exercise changes[20]. Therefore, it could be assumed that many patients were insufficiently aware of their risk behavior and were not ready to change their lifestyle. In this kind of reasoning, it is necessary to be aware that the patients included in the present study had

HbA1c levels >7% and a BMI >25 kg/m^2; thus, the study population of T2D patients was actually facing challenging multifaceted treatment.

Because behavior change theories emphasize the fact that lack of awareness is a barrier to behavioral change[12-14], removing this barrier should be the first step in lifestyle counseling. When working on awareness, lifestyle counselors should be conscious of the three stages of awareness[11]. In the first stage, patients need to be educated about unhealthy behaviors; in the second stage, patients have to realize that this unhealthy behavior applies to their own circumstances; and, in the third stage, patients should become aware that their own behavior is unhealthy. All three stages are preconditions for readiness to change health behavior. An implication of this differentiation is that lifestyle counselors should check whether patients have indeed reached the third stage of awareness.

Differences in readiness to change were based mainly on confidence in the outcomes. The patients did not differ with regard to seeing the importance of eating healthily and exercising, but patients with a misperception were less confident in changing their health behavior than others. Another Dutch study confirms this result[34], but a review concludes that recognizing the importance of the behavioral change is a strong predictor of change[35]. These inconsistencies may be attributed to the particular lifestyle behaviors that were studied or to differences in measurement[34]. For lifestyle counseling, it can make a difference if readiness to change is more affected by recognition of the importance or by confidence. If confidence is more dominant, and awareness of an unhealthy lifestyle has been realized, the focus of lifestyle counseling should be on becoming confident in reaching realistic goals[36,37], rather than on the importance issue.

The weak clustering of misperceptions of different lifestyle behaviors makes lifestyle counseling for patients with diabetes very complex because the misperception of each lifestyle behavior has to be explored separately in order to find the roots of the main problem. This result contrasts with that of a recent study that supports the assumption that those who are in a higher stage of change for one lifestyle behavior are also likely to be in a higher stage for another lifestyle behavior[38]. Recent reviews of health and food behavior change states that additional research is needed for different conditions and for more diverse populations (certain age groups)[3,5,39]. On the basis of our results, we believe that the interventions for diabetic patients should aim at various lifestyle behaviors rather than a single behavior.

Conclusions and implications

The present study is the first to report on the misperception of lifestyle behaviors and its consequences for readiness to change in T2D patients. Misperception of lifestyle behavior regarding fruit, vegetable, and fat intake, as well as physical activity, existed among T2D patients and was somewhat higher than in the general Dutch population. Patients who accurately perceived their lifestyle behavior were more ready to change it than patients who misperceived their lifestyle behavior.

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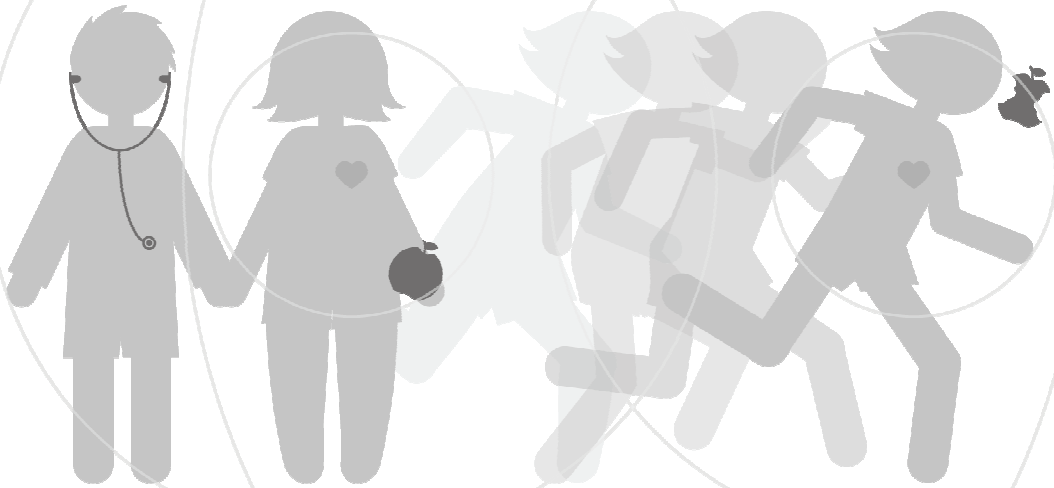
Chapter 3

Primary care nurses struggle with lifestyle counseling in diabetes care: a qualitative analysis

Renate Jansink
Jozé Braspenning
Trudy van der Weijden
Glyn Elwyn
Richard Grol



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Abstract

Background: Patient outcomes are poorly affected by lifestyle advice in general practice. Promoting lifestyle behavior change require that nurses shift from simple advice giving to a more counseling-based approach. The current study examines which barriers nurses encounter in lifestyle counseling to patients with type 2 diabetes. Based on this information we will develop an implementation strategy to improve lifestyle behavior change in general practice.

Method: In a qualitative semi-structured study, twelve in-depth interviews took place with nurses in Dutch general practices involved in diabetes care. Specific barriers in counseling patients with type 2 diabetes about diet, physical activity, and smoking cessation were addressed. The nurses were invited to reflect on barriers at the patient and practice levels, but mainly on their own roles as counselors. All interviews were audio-recorded and transcribed. The data were analyzed with the aid of a predetermined framework.

Results: Nurses felt most barriers on the level of the patient; patients had limited knowledge of a healthy lifestyle and limited insight into their own behavior, and they lacked the motivation to modify their lifestyles or the discipline to maintain an improved lifestyle. Furthermore, nurses reported lack of counseling skills and insufficient time as barriers in effective lifestyle counseling.

Conclusions: The traditional health education approach is still predominant in primary care of patients with type 2 diabetes. An implementation strategy based on motivational interviewing can help to overcome 'jumping ahead of the patient' and promotes skills in lifestyle behavioral change. We will train our nurses in agenda setting to structure the consultation based on prioritizing the behavior change and will help them to develop social maps that contain information on local exercise programs.

Background

Despite the apparent advantages of behavioral risk factor management for patients with type 2 diabetes, the predominant focus in primary care is still on curative care, and the transition is taking place at a slow rate[1]. Providing preventive service in general practice is often delegated to primary care nurses. In the Netherlands about 80% of the practices have a primary care nurse[2]. All patients in general practice can be admitted to this nurse, because health insurance companies take the cost. However, we know that patient outcomes on lifestyle advice (diet, physical activity, smoking) in general practice are poor[3-5]. The complexities of changing behavior requires nurses to shift from simple advice giving, as described in most diabetes guidelines, to a more counseling-based approach[1]. Behavioral risk factor management attempts to inform the patient about diabetes and the relation of diabetes complications to diet, physical activity, and smoking behavior. At the same time, the patient must become motivated to change his/her lifestyle and become a believer in his/her own abilities. The primary care nurse tries to promote behavioral change in a supportive, empathic, and comprehensive way, and in the meantime, she must see to it that practical barriers are overcome to facilitate the behavioral change of the patient[6]. These activities take place in the limited time span of a quarterly check-up appointment that, in the Netherlands, takes usually 15 to 20 minutes. In addition, during this time, the glucose level, blood pressure, and weight must be measured, and information about the effect of the medication is updated. Not surprisingly, some studies suggest that nurses lack time and skills to promote lifestyle changes and risk reduction[7-11]. However, the success of the lifestyle counseling depends not only on the nurse's efforts, but also on the patient's open mind and perseverance, as well as the conditions of the practice[12]. The aim of this study was to gain insight into the lifestyle counseling barriers that nurses encounter on these three levels (nurse, patient, practice). The results will be used to develop an implementation strategy to improve lifestyle behavior change for patients with type 2 diabetes in general practice. The implementation strategy will be used in a randomized controlled trial (RCT), the MILD study[13].

Methods

Study design

Semi-structured, in-depth interviews with nurses were conducted to help us better understand the specific barriers of lifestyle counseling in general practice and to help us to design and develop a more effective program for the MILD study. The nurses from the first 12 of the 70 practices that participated in the randomized controlled MILD trial[13] were invited by telephone for an interview before the trial. If more than one primary care nurse was employed in a practice, only one of them was interviewed. Each interview was conducted in the general practice of the nurse. The interviewer examined the 12 interviews to determine whether content saturation had been achieved. If saturation had not been achieved, additional interviews would have been scheduled. The medical Ethics Committee of the University of Nijmegen has granted ethical approval (16 January 2006; Reference number JvG/CMO 0116).

Data collection

The interview questions included a combination of prestructured and open-ended questions (table 1).

Table 1. Interview questions

Broad questions	What barriers do you encounter in diet counseling? What barriers do you encounter in physical exercise counseling? What barriers do you encounter in smoking cessation counseling?
Specific questions	
Patient level	What barriers occur at the patient level when you give diet counseling? What barriers occur at the patient level when you give physical exercise counseling? What barriers occur at the patient level when you give smoking cessation counseling?
Nurse level	What barriers do you encounter with skills for diet counseling? What barriers do you encounter with skills for physical exercise counseling? What barriers do you encounter with skills for smoking cessation counseling?
Practice level	What barriers do you encounter at the practice level while provide lifestyle counseling (e.g., barriers with consultation time, barriers with organization of the diabetes care)?

The nurses were asked to describe the barriers they encountered at the three levels (i.e., the nurse, patient, and practice levels) during counseling regarding

the provision of diet, physical activity, and smoking cessation. The research team discussed the precise formulation of the questions until mutual agreement was achieved. The first author (RJ) guided the discussion and used a checklist to make sure that all potential barriers were adequately discussed. The same person conducted all of the interviews, which were audio-recorded.

Procedure and data analysis

The interviews were transcribed verbatim. Data analysis were done according to the framework approach[14]. Two researchers (RJ and MdB) independently reviewed the transcripts and classified the comments according to a predetermined framework based on several theoretical reflections on behavioral change as described by Grol et al.[15]. In cases of disagreement, consensus was achieved via discussion with a third researcher (JB). In this framework, the three main levels of barriers to lifestyle counseling (the nurse level, the patient level, and the practice level) were subdivided into several categories. At the nurse level, the categories were awareness, knowledge, attitudes, motivation to change, and behavioral routines. At the patient level, the categories were knowledge, attitudes, skills, and compliance. At the practice level, the categories were organization of care processes, staff, capacities, resources, and structures[15]. Additional categories were formulated for barriers that did not fit into the categories of the original framework.

Results

Characteristics of primary care nurses

Table 2 summarizes the characteristics of the primary care nurses. All of the nurses initially invited to participate in the trial agreed to take part. In one general practice, we interviewed two nurses as this was preferred by the practice over an interview with only one. A total of 13 primary care nurses were interviewed.

The mean age of the nurses was 44 years (range 27–51 years), and all were women. They had an average of 3.0 years (range 0.5-4.5 years) of experience with diabetes consultation. Six of the nurses (50%) had an average of 12 years (range 2-24 years) of experience as practice assistants in the Netherlands. A practice assistant is somebody who supported the general practitioners and worked predominantly as receptionist and administrative assistant[16]. The participating nurses were trained as a nurse in a 3 or 4 years program (middle or

higher education) and specialized in primary care for respectively another 2 or 1 year program.

Table 2. Study population

Characteristics of primary care nurses	*n*=13
Men/women	0/13
Mean age in years (range)[1]	44 (27–51)
Primary care nurses who were formerly practice assistants (percentage)[1]	6 (50%)
Mean years of experience as practice assistant (range)[1]	12.3 (2–24)
Mean years of experience working with diabetes (range)[1]	3.0 (0.5–4.5)

[1] After the interviews, one nurse withdrew of the study. Her characteristics were unknown.

Interviews

The last two interviews added no new information. No more practices were invited for an interview because saturation had been reached. A few adjustments were made to the predetermined framework during the analysis. The categories 'awareness' was omitted at the nurse level because the nurses were well aware of the necessity of changing their method of lifestyle counseling that is why they enrolled in our study. At nurse level the 'motivation to change' category was substituted with 'skills' which described the responses more accurately and was congruous with the category at patient level (table 3). At practice level, three categories were combined in order to prevent overlap (table 5) and we subdivided categories based on the different issues raised (tables 3, 4, 5).

Table 3. Barriers to lifestyle counseling in diabetes care at the nurse level

Categories	Knowledge	Attitude	Skills	Behavior routines
Sub-categories	1. Lack of knowledge about diet and physical activity	1. Lack of motivation 2. Relationship with patients 3. Lack of empathy 4. Stress caused by pressure of time	1. Lack of communication skills 2. Making concrete plans in a structured manner 3. Working faster than patients	1. Involving patients in decision-making

Table 4. Barriers to lifestyle counseling in diabetes care at the patient level

Categories	Knowledge	Attitude	Skills	Compliance
Sub-categories	1. Little insight and knowledge of one's own behavior and health 2. Language barriers 3. Wrong information from the environment (social influences)	1. Unwillingness caused by: a. Not liking to change or not wanting to change b. Age c. Previous experience with dietician 2. Excuses 3. Habits 4. Cultural difference	1. Physical restrictions 2. Financial restrictions 3. Location of exercise programs 4. Addiction to smoking 5. Noncompliance with advice 6. Psychosocial troubles	1. Lack of immediate results 2. Difficult moments 3. Potential relapse 4. Lack of discipline in maintenance

Table 5. Barriers to lifestyle counseling in diabetes care at the practice level

Categories	Organization of care processes, staff, and capacities	Resources	Structures
Subcategories	1. Lack of time 2. Poor cooperation between primary care nurse and other health providers	1. Local exercise map missing	1. Insufficient information material 2. The stop-smoking protocol is inadequate

The nurse level

KNOWLEDGE. Some nurses reported lacking sufficient knowledge about physical activity, smoking cessation, and even more notable, about specific diet advice in order to provide adequate lifestyle counseling. They also explained that it is a dietician's task to give specific diet advice to patients. However, some patients are not willing to see a dietician. In such cases, the nurse felt a need to give the diet advice to the patient.

> *"Some patients have had bad experiences with dieticians and refuse to go to them. This means that I have to get down to the diet advice. I can tell the patients what is good or bad for them, but for specific diet advice they still have to go to the dietician." (N2)*

The knowledge deficiency felt masks a shortage of coordination capability with dietician and of communication skills of convincing explanation to patients.

ATTITUDES. Some nurses mentioned they sometimes lack motivation themselves because they have to repeat the lifestyle message again and again, and they have little hope that the patient will change. That makes them feel very

powerless. Other nurses did not like to be judgmental and were hesitant to discuss lifestyle behavior change if they thought that would put the relationship with the patient at stake. Another barrier nurses mentioned is lack of empathy. This can occur when nurses do not understand why it is so difficult to change a specific lifestyle which is not a barrier for themselves. Furthermore, they found it difficult to be patient and listen carefully when they were stressed for time.

> *"It is very difficult for patients to change their lifestyles. I have to tell them the same thing all the time, mostly without any result. This makes me feel powerless." (N3)*
>
> *"I like to see the patients pleased to come back, so I want to have a good relationship with them. Sometimes I am too soft. This is wrong because I have to help patients change their lifestyles." (N3)*

SKILLS. Nurses repeatedly highlighted a deficiency in their lifestyle counseling skills. They do not know how to develop a concrete and structured action plan in cooperation with the patient. They also reported having difficulties in adapting their counseling to the stage in which the patient is.

> *"I do not know what the best way is to counsel patients. At the end of the consultation, I must have a concrete action plan, such as: eat less high-fat cheese. It is difficult to make things concrete and do this in a structured manner." (N11)*
>
> *"Sometimes I supply information too fast. The patients are in an earlier stage of change." (N13)*

It seems that the nurses are jumping ahead of the patient. Nurses had false or too high expectations for lifestyle change by patients. This results in a righting reflex where they push too hard for change, resulting in resistance of the patient. Nurses explicitly told us that they would like to have some skills to overcome this barrier.

BEHAVIORAL ROUTINES. General practice did not had a long history of providing preventive services to patients. For that reason, primary care nurses reported having difficulties getting rid of old or inappropriate routines. For making, but in practice they regularly gave simple lifestyle information and advice to patients.

"Some patients can hardly move. I look for alternatives to solve the barrier, but I have to give these patients time to look for a solution themselves." (N7)

The patient level

KNOWLEDGE. Nurses thought that while patients have a general feeling of the urgency to change, they lack insight into their lifestyle behavior, health, and, in particular, the effects of their diet. Since patients think they know how to live healthy, they often refuse to see a dietician. Furthermore, the nurses thought that language could be a barrier for patients from other cultures and for patients who have a low level of understanding. Misinformation from peers could also interfere with lifestyle counseling.

"Patients do not know what carbohydrates and glucose are, or they think they eat healthful food while it is actually fatty. Some patients refuse to see a dietician because they think that they already know everything there is to know about diet." (N4)

"Patients from other cultures do not understand the lifestyle counseling because they do not master the Dutch language. However, some Dutch people do not understand the counseling either." (N2)

"The social control over diet is very strong among people in small villages. Sometimes, diabetes is discussed at birthday parties where patients can give each other incorrect pointers about food." (N8)

ATTITUDES. According to the nurses, the unwillingness of patients to change their lifestyle is based on a general aversion to change and previous experience with a dietician. This was seen more often among the elderly. Furthermore, nurses thought that patients search for excuses not to give up their habits.

"Patients think it is very difficult to stop smoking, but most patients who actually stopped thought afterwards that it exceeded their expectations." (N3)

"It is difficult to motivate older patients with diabetes to eat healthful food — they say: 'I am 75 years old and I do not intend to go on a diet,' 'I have reached a good old age with my own eating habits,' or 'If I live 10 years less — so what? I'm alone anyway." (N10)

"Patients with diabetes are often not used to physical activity, so it is very difficult for them to start exercising at an older age. They

search for excuses: 'I have a backache', 'The weather is bad', or 'I'm tired after a busy workday.' Any excuse not to move.' (N5)

The expressions of the patients indicate the need to patient-centeredness, but nurses did not report opportunities to start a discussion on patients motivation to change lifestyle behavior.

SKILLS. Most patients with type 2 diabetes are older people with physical disabilities and sometimes low incomes. The nurses thought that it was not easy for a patient to increase his/her level of physical activity and not possible at all when there is no gym or fitness center in the neighborhood. Furthermore, smoking is an addiction. The nurses said that sometimes patients try to quit smoking by cutting back, but quickly relapse. Patients with psychosocial barriers often do not want to stop smoking, according to the nurses.

"Patients with physical restrictions hardly exercise, even if they want to; they cannot afford to go to a gym. It is very expensive." (N1)

"People have to travel considerable distances because there is no gym or exercise club in their neighborhood." (N9)

COMPLIANCE. The compliance-related barriers that the nurses mentioned are lack of immediate results, lack of discipline for maintenance, potential for relapse, and difficult moments such as stress situations and situations in which other people lure patients into unhealthy behaviors.

"A change of lifestyle does not immediately lead to positive results. Patients find it difficult to deal with these challenges and gradually lose heart, which often results in a relapse to an unhealthy lifestyle." (N13)

The practice level

ORGANIZATION OF CARE PROCESSES, STAFF, AND CAPACITIES. Some nurses reported lacking sufficient time for additional tasks such as keeping pace with new developments. Practice management will not provide more time because it is expensive. The cooperation between health providers was good in most cases, but some nurses felt that they did not get enough feedback from the dietician. There was also a lack of clarity with regard to roles and responsibilities between the nurses and dieticians. The nurses sometimes simply told us, for instance,

that diet counseling is the dietician's task. A much-needed consultation with the general practitioner was also sometimes skipped because of an emergency.

> *"There is not enough consultation with the dietician. I often do not know what kind of diet arrangement has been made with the patient. Or sometimes the general practitioner has to attend to an emergency and our conversation is left unfinished." (N2)*

RESOURCES. A so-called local exercise file is an overview of local sport schools and other physical activity facilities in the area. Exercise files were not available in some of the general practices resulting in nurses having little knowledge of the local exercise programs for patients with diabetes. They also did not know whether reimbursement for the exercise programs was possible.

STRUCTURES. Nurses told us that they lack high-quality patient education materials for effective lifestyle counseling. In addition, some nurses found the protocol used for smoking cessation inadequate for optimal counseling. They have heard from colleagues that there is a better protocol, but the course is very expensive – too expensive for their general practice.

Discussion

Nurses perceived considerable barriers to lifestyle counseling in general practice. We looked separately to the three areas of lifestyle (diet, physical activity, and smoking cessation), but did not see differences in barriers named. So we decided to focus on the general level. There was significant agreement between the nurses on the barriers reported. As expected, barriers include insufficient time and lack on counseling skills[7-11]. However, most barriers mentioned by nurses were on the level of the patient. Nurses reported that patients have limited knowledge of a healthy lifestyle and limited insight into their own behavior. Moreover, they have little motivation to modify their lifestyles or the discipline needed to maintain an improved lifestyle.

The results of the current study are consistent with previous research that explores the barriers that healthcare providers encounter during patient counseling. Considering the barriers at the patient level, general practitioners mention the excuses that patients use to avoid having to change poor health habits[11]. Other healthcare providers also frequently report difficulties with patient motivation and unwillingness to change[4,9,11,17,18]. It is important that the

providers of lifestyle counseling be familiar with the patients' barriers[4,11,19,20]. The participating nurses in our study are well informed about which barriers much be confronted during the provision of lifestyle counseling. The nurses were very willing to help patients with regard to lifestyle changes and considered it an important part of the care for patients. Nonetheless, it is difficult to deal with certain patients' barriers, and nurses sometimes feel powerless when patients do not attain the goals that have been set. This may frustrate both patients and nurses, reduce the nurses' empathy for at least some patients, and reduce their motivation to counsel patients in general. This is in line with research showing that general practitioners who try to provide good diabetes care via the presentation of evidence-based recommendations experience considerable frustration when patients do not adopt or adhere to these recommendation[11]. It is very difficult to convince patients of the necessity of lifestyle changes. Nurses may have to motivate patients to change, but are not prepared for this task. Furthermore, when possible solutions to overcome these barriers are discussed, nurses suggested that extra training in counseling skills might help them motivate patients. Primary care providers in other studies also report a lack of skills for facilitating behavioral changes as a barrier at the nurse level[11,21-23]. The nurses interviewed for this study had a specific education for general practice. They were trained in counseling techniques. However, training in communication techniques alone is not enough to change lifestyle behavior. Karhila et al. suggest that nurses might need to become more aware of their counseling practices in routine situations through conscious effort for self-evaluation[24].

Professionals and patients in general practice have indicated a preference for a more patient-centered approach[25]. However, changing from health education is not an easy task. Allowing patients the freedom to make their own decisions about their health behaviors can be a difficult task for nurses[24]. Nurses feel a professional responsibility to accurately advise the patient rather than allow the patient to make a decision for themselves. Ineffective lifestyle counseling was also attributed to lack of time for the nurses providing such counseling, which is a well-known barrier at practice level[26,27]. The nurses told us that, due to this lack of time and insufficient knowledge of diet counseling, they could not really address the patient's diet[28]. However, in some studies a majority of professionals reported little or no increase in time demands[29]. Furthermore, some nurses thought that diet counseling was not their task but, rather, the

dietician's task. Given that the cooperation between dietician and nurse is not optimal, patients are then left with, possibly critical, diet questions and a lack of help to improve their diets.

The most important finding is that the nurses notify a lot of barriers on the patient level. This can be explained by two factors. First, nurse tend to have false or too high expectations for lifestyle change by their patients (jumping ahead of the patient), resulting in resistance of the patient. Secondly, the provision of simple lifestyle information and advice was the predominant strategy used by primary care nurses, as evidence by the contradictions in the nurses' language use: 'counseling' versus 'I have tell them the same thing all the time', 'advice', 'sometimes I'm too soft', 'supplying information'. While advice giving is an important task in lifestyle counseling, it is associated with increased patient resistance if unsolicited. Lifestyle counseling that can help to overcome these processes is motivational interviewing. Motivational Interviewing is a patient-centered, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence[30]. Research has shown that motivational interviewing is an effective strategy in implementing recommendations on lifestyle[7,31]. This strategy should focus on brief consultations and seems to be a great opportunity to solve many barriers mentioned.

Two methodological issues need to be addressed. First, as the nurses joined the study voluntarily, it might be that they are not a representative sample of the general population of nurses. Thus there may be limits to generalizing these findings. However, findings from other studies suggest that most providers of care experience similar barriers[11,18,21,32]. Second, it was sometimes difficult to fit the data into the framework. Primary care nurses mentioned the "absence of a local exercise file" and "unsuitable leaflets regarding lifestyle recommendations" as barriers at the practice level. These, however, could also be classified as a "shortage of knowledge" at the level of the nurse. Our strategy was to classify them according to the category that the nurses mentioned.

Conclusions

The traditional health education approach is still predominant in primary care of patients with type 2 diabetes. Nurses were often inclined to take over the responsibilities of the patient too quickly, while the lifestyle guidance of

patients with diabetes is more effective when the responsibility is shared. The nurses also found it difficult to motivate patients, and reported a need to improve their own counseling skills. What nurses require are concrete tools to increase patient adherence to recommended lifestyle changes and ways to build these tools into daily care. Given the limited proportion of patients who actually change their behavior, lifestyle counseling emerges as an unrewarding part of the primary care nurse's job.

Based on our results we will develop an implementation strategy, built on motivational interviewing, that can help to overcome 'jumping ahead of the patient' and promotes skills in counseling for lifestyle behavioral change. We also make room for agenda setting of the patient to structure the consultation based on prioritizing the necessary behavior change. We will train our nurses in motivational interviewing as well as agenda setting and help them with developing social maps that contain information on local exercise programs.

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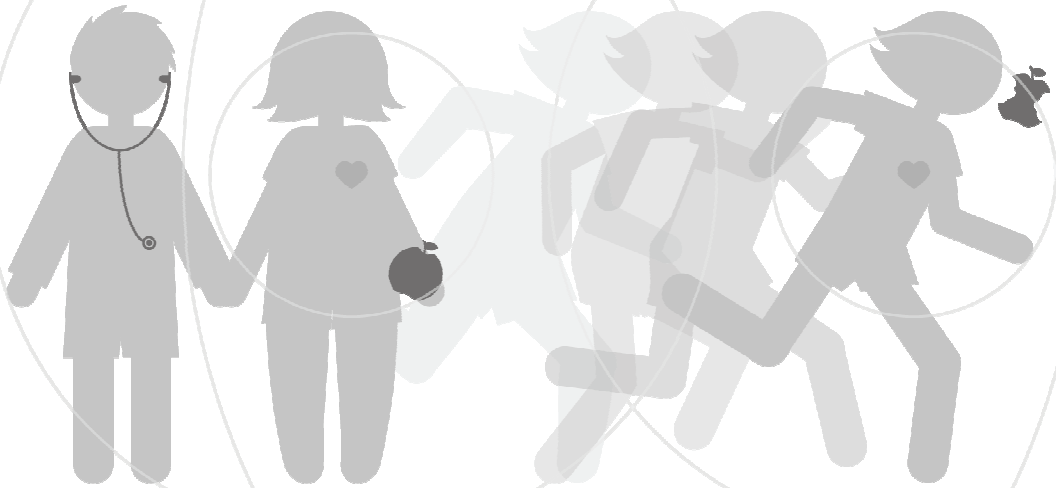
Chapter 4

Nurse-led motivational interviewing to change the lifestyle of patients with type 2 diabetes (MILD-project): protocol for a cluster, randomized, controlled trial on implementing lifestyle recommendations

Renate Jansink
Jozé Braspenning
Trudy van der Weijden
Louis Niessen
Glyn Elwyn
Richard Grol



BMC Health Services Research 2009; 9: 19

Abstract

Background: The diabetes of many patients is managed in general practice; healthcare providers aim to promote healthful behaviors, such as healthful diet, adequate physical activity, and smoking cessation. These measures may decrease insulin resistance, improve glycemic control, lipid abnormalities, and hypertension. They may also prevent cardiovascular disease and complications of diabetes. However, professionals do not adhere optimally to guidelines for lifestyle counseling. Motivational interviewing to change the lifestyle of patients with type 2 diabetes is intended to improve diabetes care in accordance with the national guidelines for lifestyle counseling. Primary care nurses will be trained in motivational interviewing embedded in structured care in general practice. The aim of this paper is to describe the design and methods of a study evaluating the effects of the nurses' training on patient outcomes.

Methods/Design: A cluster, randomized, controlled trial involving 70 general practices (35 practices in the intervention arm and 35 in the control arm) starting in March 2007. A total of 700 patients with type 2 diabetes will be recruited. The patients in the intervention arm will receive care from the primary care nurse, who will receive training in an implementation strategy with motivational interviewing as the core component. Other components of this strategy will be adaptation of the diabetes protocol to local circumstances, introduction of a social map for lifestyle support, and educational and supportive tools for sustaining motivational interviewing. The control arm will be encouraged to maintain usual care. The effect measures will be the care process, metabolic parameters (glycosylated hemoglobin, blood pressure and lipids), lifestyle (diet, physical activity, smoking, and alcohol), health-related quality of life, and patients' willingness to change behaviors. The measurements will take place at baseline and after 14 months.

Discussion: Applying motivational interviewing for patients with diabetes in primary care has been studied, but to our knowledge, no other study has yet evaluated the implementation and sustainability of motivating and involving patients in day-to-day diabetes care in general practice. If this intervention proves to be effective and cost-effective, large-scale implementation of this nurse-oriented intervention will be considered and anticipated.

Background

Professionals' performance in lifestyle counseling is suboptimal, yet it is very important that healthcare providers promote healthful behaviors for patients with type 2 diabetes[1,2]. There are studies indicating that healthful diet and physical activity decrease insulin resistance and improve glycemic control, lipid abnormalities, and hypertension, thereby lowering the risk of cardiovascular disease (CVD)[3-6]. Smoking is known to be particularly dangerous; it doubles the risk of CVD for those with and without diabetes[7]. Lifestyle counseling requires more focused support for professionals so that they can adequately support their patients[8,9].

With the increasing prevalence of diabetes due to aging and the increasing average weight in the population, the problems of lifestyle counseling are becoming more urgent[9]. Diabetes mellitus is a major cause of morbidity and mortality worldwide. About half a million people are known to have diabetes in the Netherlands, and this number is expected to increase by 36% in the next 20 years[10]. The age- and sex-adjusted prevalence of type 2 diabetes is 2.9%; 3.1% for women and 2.7% for men[11]. Patients aged more than 70 years account for almost 50% of all patients with type 2 diabetes[11].

Effective diabetes care is based on two elements: structured care and a patient-centered approach[12-14]. These elements lead to improvements of patient outcomes and process outcomes, and they play an important role in lifestyle counseling for diabetes patients[15-17]. In the Netherlands, diabetes care is provided mainly in primary care (80–90%), and in most practices, a primary care nurse has the tasks of providing lifestyle counseling in a structured manner and involving patients in managing their disease[18,19]. Nevertheless, some studies suggest that many healthcare providers, nurses included, lack the skills to promote lifestyle change[20-24]. A practical tool such as the patient-oriented counseling technique of motivational interviewing (MI) can contribute to implementing the lifestyle recommendations[20,25]. Controlled trials in general practices have shown that MI is an effective strategy in the treatment of various diseases[26-30]. However, just training primary care nurses in MI will not be sufficient; it is important to embed MI in an implementation strategy[13].

There is a wide range of implementation strategies aimed at improving the provision of diabetes care in primary care. Multifaceted professional interventions (such as counseling, auditing, and feedback) and organizational interventions (such as revision of professional roles, changes in medical record

systems, and arrangements for follow-up) that facilitate the structured and regular review of patients have proven to be effective in improving care[13]. However, very few studies have focused on integrating some of these implementation strategies effectively into professional behavior in daily work in general practice.

Our Motivational Interviewing to Change the Lifestyle of Patients with Type 2 Diabetes (MILD) Study is intended to improve type 2 diabetes care in accordance with the national guidelines for lifestyle counseling by having primary care nurses, who will be trained in lifestyle MI and who will implement structured care in general practice. The impact of the implementation strategy will be evaluated in various ways. First, the effect of the implementation strategy on the nurses' care and the relevant patient outcomes will be examined and compared with those of usual care. Second, there will be a process evaluation of the exposure of the implementation strategy and its feasibility. Third, since this study will determine both the effects and the costs of the implementation strategy, we plan to evaluate it economically to establish the cost-effectiveness. The aim of this study protocol is to describe the design and methods of a study to evaluate the effects, costs, process, and cost-effectiveness of an implementation strategy for motivating and involving patients in lifestyle issues as a part of their diabetes management.

Our research questions will be:

1. What is the effect of an implementation strategy aimed at the routine MI by primary care nurses compared to usual care with regard to:
   (a) The care process
   (b) The metabolic parameters, such as glycosylated hemoglobin (HbA1c), blood pressure, and lipids
   (c) Lifestyle changes; diet, exercise, smoking, and alcohol consumption
   (d) Health-related quality of life
   (e) Patients' willingness to change behaviors? [Effect evaluation]
2. To what extent do primary care nurses take part in the implementation strategy, and is the strategy feasible in the view of patients and nurses? [Process evaluation]

3. What is the incremental cost-effectiveness ratio of our implementation strategy compared with that of the usual care of a primary care nurse? [Economic evaluation]

Methods/Design

Study design

The study is a cluster, randomized, controlled trial involving 70 general practices and 700 patients with type 2 diabetes in the Netherlands. Each practice is staffed with a primary care nurse who will be allocated to either:

- The control arm of practices in which patients with diabetes receive only usual care from the primary care nurse.
- The intervention arm of practices in which patients with diabetes receive care from nurses who will be skilled in MI and authorized to use it.

We will include all appointments for each patient (the guidelines require four appointments), so that each patient will be followed for 14 months.

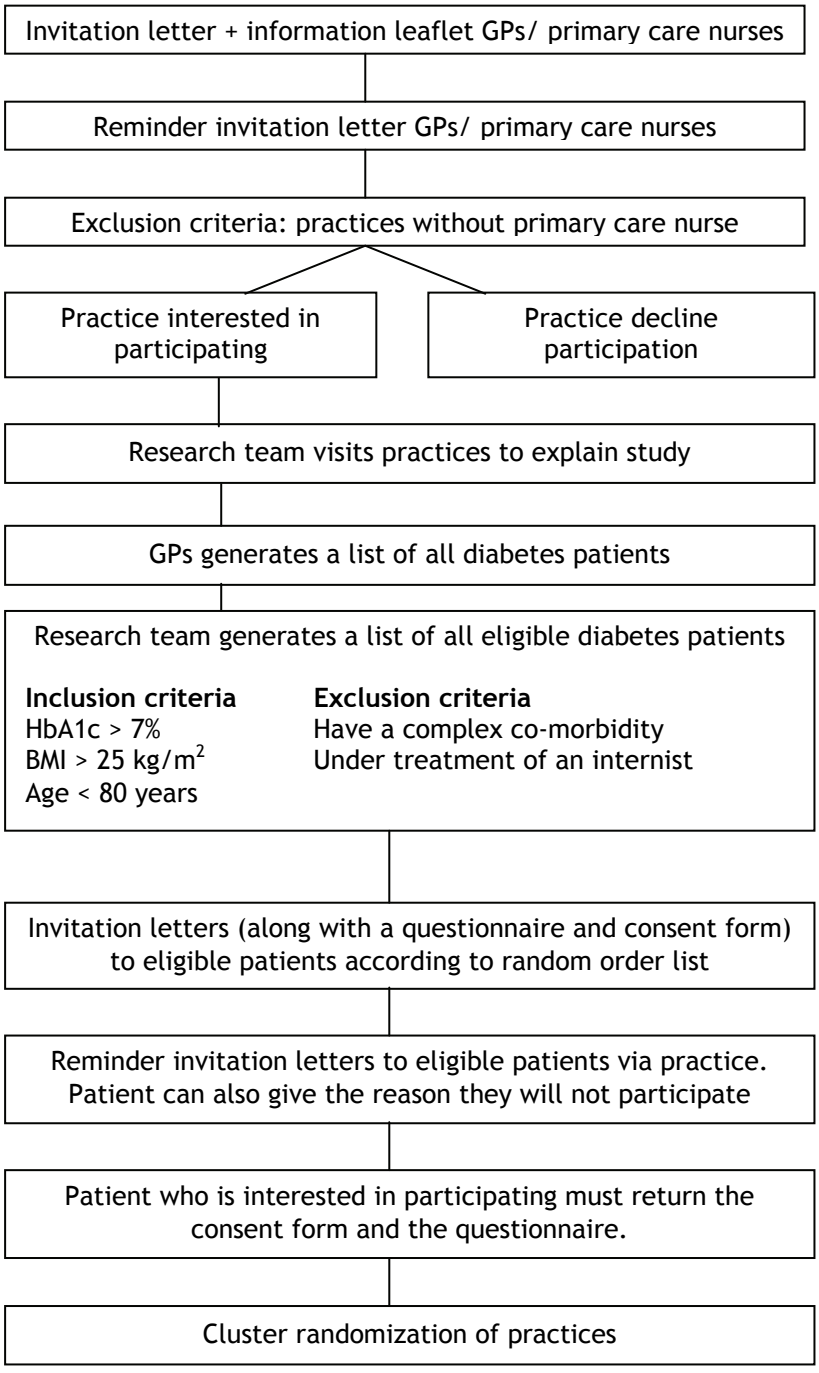
Ethical approval and informed consent

The Medical Ethics Committee of the University of Nijmegen has granted ethical approval. The trial is registered as ISRCTN68707773[31]. The general practitioner (GP) and the research team will send a letter of information about the project to each eligible patient. The privacy of the participating patients will be protected, and all data will be coded and processed anonymously. It will be made clear in the informed consent form that each patient can stop his or her participation in the study at any moment without any consequence for the quality of his or her usual diabetes care. The patient will be asked to sign the informed consent form and return it to Nijmegen University to allow further contact regarding the research.

Recruitment of general practices and patients

The trial will be carried out with general practices and their patients with diabetes. Figure 1 shows the pathway with which general practices and patients will be recruited.

Figure 1. Flowchart of the process for recruiting general practices and patients with diabetes



General practices

Practices in the south of the Netherlands will receive a letter of invitation with an information leaflet about the study. General practices that do not employ a primary care nurse will be excluded from the study. A member of the research team (RJ) will visit all practices that express their intention to participate. At least one GP and the primary care nurse of a practice willing to participate will be present during the appointment. We will explain the study in detail and provide them with a full information package describing the aims, methods, and expected outcomes of the study. Non-responders will be reminded by letter 4 weeks later. Invitation letters will be sent in several rounds until we find 70 general practices that will participate.

Patients

Patients with type 2 diabetes will be eligible to participate if they are younger than 80 years, their most recent (frequently no longer than a year ago) HbA1c concentration is more than 7.0%, their body mass index is more than 25 kg/m^2, and they are receiving care from a general practice that employs a primary care nurse. Patients with complex coexisting medical conditions (e.g. mental illness or end-stage cancer) and those being treated by an internist will be excluded. Two members of the research team will make a list of all eligible patients in the participating practices by extracting means data from medical files. Each of these patients will be sent a letter with the GP's invitation to participate in the study. The letter will include information about the design of the study, confidentiality of data, the voluntary character of participation, a questionnaire, and the informed consent form. The patients will be asked to respond by returning the signed informed consent form and the completed questionnaire to the research team. Four weeks later, a reminder will be sent to patients who have not responded. Non-responders will be asked to give their reasons for not participating, so that we can compare the participating and non-participating groups.

Randomization

General practices will be the unit of randomization. An independent person at Radboud University will centrally randomize the 70 general practices in a randomized block design, after the type of practice and urbanization level have been stratified.

Sample size

In a regular practice, the proportion of patients with diabetes who have an HbA1c concentration greater than 7.0% is about 48%[32]. Lifestyle intervention studies have consistently shown that modest changes in the HbA1c concentration can reduce the progression from impaired glucose tolerance to diabetes by about 50%[33]. Therefore, we will aim our program to reduce the proportion from 48% to 24% (50% relative risk reduction). With five patients in each practice, 30 practices in each arm of the study will be needed, if we assume an intercluster correlation of no more than 0.05[34], and set alpha at 0.05 and beta at 0.20.

We also calculated our power on another main outcome; the extent to which patients participate, or are willing to participate, in a program of diet, exercise, and smoking cessation. We predict that the willingness to participate in such a program can at least be tripled on the basis of comparable results of intensive stop-smoking programs in general practice[35]. Just as in smoking cessation studies, we assume that the success of lifestyle counseling in usual care is 5% (relative risk reduction). A power calculation based on these assumptions shows that we need a total of 68 practices (34 in each arm), with 5 patients in each practice for an implementation strategy based on MI. To answer the research questions, we will take a random sample from the target group; and to take dropout into account, we will include 35 practices in each arm with 10 patients in each practice. Recruitment of 70 practices (700 patients) will be feasible.

Control group conditions/usual care

The primary care nurses in the control group will not have access to the implementation strategy. They will be offered an opportunity to join the training program at the end of the study. The nurses will be instructed to administer usual care consistent with current diabetes guidelines. These guidelines state that, in usual care, the GP pays attention to complaints, glucose regulation, current cardiovascular risk, and the early identification of complications. Patients without complaints and with good metabolic regulation will be invited to check-ups every 3 months. Once a year, the GP will pay extra attention to specific items noted during the consultations[18].

Three-monthly check-ups

At the check-up, the GP will ask about well-being, symptoms that indicate hyperglycemia or hypoglycemia, complications in diet and exercise counseling, and medication. The GP will note the patient's weight. The fasting blood glucose value will also be determined every 3 months[18].

Annual check-ups

The annual check-up will be extensive. The GP will ask about eye complications, cardiovascular problems, sexual problems, possible causes of and options for treatment, etc. Furthermore, lifestyle counseling (about smoking, physical activity, and alcohol use), physical examination (body weight, blood pressure, and condition of the feet), chronic complications, and laboratory research will be reviewed. The laboratory work will provide values for the fasting glucose, HbA1c, creatinine concentration and clearance, lipid spectrum, and urine albumin/creatinine ratio (or albumin concentration)[18].

The intervention

In addition to instruction for adhering to the prevailing guidelines for diabetes care as described in usual care, the primary care nurses in the intervention practices will receive information about the various components of the implementation strategy: (1) training in MI, (2) adapting the diabetes protocol to local circumstances, (3) introducing a social map for support of lifestyle change, and (4) practice tools for maintaining the training program (box 1). The "diabetes protocol", "social map" and "MI training" will be components of the training program, which consists of 4 half-day training sessions spread over the 1st half year. Primary care nurses will attend these sessions in groups of 5 to 8 people outside the practice. The "practice tools" will be a component of the follow-up and will start after the training program. The implementation strategy will start in the first training session.

Box 1. Implementation strategy for primary care nurses

Training program (4 half-days, spread equally over 6 months)

(1) Training primary care nurses in the **principles of motivational interviewing (MI)** in order to encourage patients with diabetes to adhere to lifestyle guidelines. The following components will be discussed:
- *Agenda setting* to make consultations more structured and to draw up concrete appointments
- *Building motivation for change: importance and confidence*
- *Asking open questions, listening reflectively, affirming, summarizing, and eliciting change*
- *Expressing empathy, developing discretion, rolling with resistance, and supporting self-efficacy.*

(2) Adapting the **diabetes protocol** to local circumstances.

(3) Introducing a **social map** for lifestyle change to primary care nurses. The map is an overview of all available organizations and their treatment programs to help patients choose, for example, the right sport school or physiotherapist.

Follow-up (8 months)

(4) **General practice tools** for primary care nurses for maintenance of the training program, which include:
- An *instruction chart with counseling techniques*, as a reminder to help patients change
- *Record keeping* of consultation data and behavioral change of the patients, which primary care nurses must do.
- Recommendations for *regular telephone follow-ups* for diabetes patients, which will be monthly in the 1st half year and then will probably decrease.
- A *help desk*: the research team will call the primary care nurse three times to inquire about their development of health counseling and nurses can call the research team for information.
- A *follow-up meeting* to receive feedback about their own video recording.

Motivational interviewing

Motivational interviewing (MI) will be introduced as a tool for behavior change. The MI counseling technique is patient oriented and suitable for brief office visits, and it can be used to improve patient adherence to diet, exercise, and smoking counseling in daily routine[36]. Since the MI technique plays an important role in our study protocol, we have described it in more detail in box 2.

Box 2. Description of motivational interviewing

Motivational Interviewing (MI) is formally defined as "a client centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence" (Miller and Rollnick, 2002). The MI approach is distinguished from some other counseling models; it is not focused on 'I will change you', but on 'If you wish, I can help you change'. The four guiding principles of MI are (1) express empathy, (2) develop discrepancies, (3) roll with resistance, and (4) support self-efficacy.

1) "Expressing empathy involves providing clients with an atmosphere of respect and acceptance of their position. The technique used is reflective listening and this is generally considered the foundation of MI and is recommended throughout the counseling process." Example script: 'Sounds like working on getting exercise and keeping up your blood glucose is very demanding. I think it is natural to struggle sometimes. What is it like for you? Are there any obstacles that make it particularly difficult?'
2) "Develop discrepancies involves creating a 'gap' between the client's current behaviour and their broader goals, thus cultivating motivation for lifestyle change. When the client recognizes such discrepancies, a certain level of discontent arises that makes change more likely to occur. Discrepancies are developed by exploring the client's important life values and reviewing how their current behaviors affect their ideal lifestyle". Example script: 'So on the one hand you are not sticking with your exercise program, because it's hard to find time but on the other hand you think exercise would make you feel better and help manage your blood glucose level. It sounds like managing diabetes is pretty important to you. How do you think having a high BMI affect this overall? Where do the exercises fit in here?'
3) "Directly challenging resistance is counterproductive to lifestyle change because it typically results in the client defending their current state of affairs. Rather, resistance should be rolled with and channelled instead of confronted. Rolling with resistance invites the client to consider a new perspective versus having it imposed". Example script: 'It can be very frustrating to make all these changes, especially when it has becoming a habit and others giving you hard time. I think it is completely normal to want to go back to old habits when times are tough. May I tell you about some different options that have been worked well for others?'
4) "Self-efficacy, or one's confidence in the ability to change a specific behaviour under difficult circumstances, should be supported whenever possible because it is one of the best predictors of treatment outcome. Self-efficacy can be strengthened by affirming past success (i.e., reinforcement), presenting success stories of others (i.e., modelling), and expressing their belief in the client's potential to change". Example script: 'I see you have been keeping up your blood glucose level despite the difficulties adhering to your diet and exercises. It looks like you had a lot of initial success when you began making health changes. What worked so well for you then? Sometimes a setback can actually be a good thing.'

Content

The first step in MI is to set the agenda for the consultation together with the patient[36]. "Agenda setting" will be an issue to keep in the back of your mind from the very beginning of the first interview. The basic question here will be, "What are we going to talk about?" The patient will be encouraged to choose one or more key items in this agenda setting. This will make consultations more

structured and will lead to a more concrete action plan. After this, the primary care nurse will assess the patient's current behavior and motivation for change by rating and exploring importance and confidence with respect to the chosen key items. She will do this by reflective listening, summarizing, asking open questions, scaling, supporting self-efficacy, rolling with resistance, expressing empathy, and developing discrepancy. If there is a need and sufficient motivation for change regarding one or more items, the primary care nurse will consult with the patient to select one item as the goal for behavior change.

Structure

The MI training will be developed in cooperation with a professional trainer, who will also tutor the complete training program. Activities will include group discussions and role plays on specific skills such as use of the ambivalence, supporting self-efficacy, and reflective listening. Video fragments created by a professional involved with MI will be shown, and some video recordings of primary care nurses will be discussed to learn about good and not so-good points of lifestyle counseling. After each training session, the primary care nurses will have homework: they will study the theory from the training session and apply this theory to at least two patients with diabetes (cases). The instruction to the primary care nurse will be to write down the two consultations and to take these cases to the next training.

Protocol for diabetes care

The Dutch guidelines for type 2 diabetes mellitus give recommendations for diagnostics and management to patients with diabetes[18]. However, some recommendations, such as which tasks are to be delegated to primary care nurses and how long a diabetes consultation should last, will have to be adapted to each practice in a localized protocol. During the training, the differences and agreements of several diabetes protocols from general practices will be discussed with the primary care nurses in order to show that there is more than one way to carry out diabetes care.

Social map

Practical information will be needed in the practice, e.g., about local diet and exercise programs, so that patients can learn about these programs from the

primary care nurse. They will be encouraged to set up a network for (1) contacting local dieticians to make appointments about referral and treatment plans, and (2) gathering local exercise programs and determining whether local government offices or other parties will fund exercise programs (leading to a social map). During the training, the social map will be discussed, and primary care nurses who already have a social map in the general practice will share their ideas with other primary care nurses who do not have a social map in their general practice.

Practice tools

The following educational and supportive tools will be distributed after the training program: a laminated instruction chart with counseling techniques, record keeping information, and recommendations for regular telephone follow-ups to patients with diabetes; a help desk for primary care nurses; and a follow-up meeting for primary care nurses. We will ask the primary care nurses to keep up a record of consultation data, such as the stage of change of the patient with regard to diet, physical activity, smoking, and alcohol. The record keeping, like the instruction chart, will be a useful and practical reminder during consultations. The trainer will advise the primary care nurses to monitor patients every 3 months according to the treatment guidelines, to do MI, and to follow up regularly by telephone, which will be every month for the 1st half year and will probably decrease after that.

The research team will function as a help desk; primary care nurses will be able to call the research team for information, who will follow up with three phone calls to inquire about the development of the primary care nurses' health counseling. The nurses' difficulties with the counseling technique will be mentioned to this team and they will look for solutions. When primary care nurses consider a follow-up meeting (an afternoon) important, this meeting will take place. These supportive tools will be used in the follow-up period for maintenance of the MI training.

Effect evaluation

The aim of the effect evaluation will be to determine whether the implementation strategy has achieved the intended effects on the care process and the patients' clinical outcomes. The research question will be, "What are the effects of an implementation strategy aimed at improving MI skills of

primary care nurses compared to the effects of usual care on the care process, the metabolic parameters (such as HbA1c, blood pressure, and lipids), lifestyle (diet, exercise, smoking and alcohol consumption), health-related quality of life, and patients' willingness to change their behavior?"

Variables and measures

Figure 2 and table 1 give a detailed overview of the outcome measures and instruments.

Figure 2. Flowchart showing relationship of the strategy, characteristics, variables, and indicators

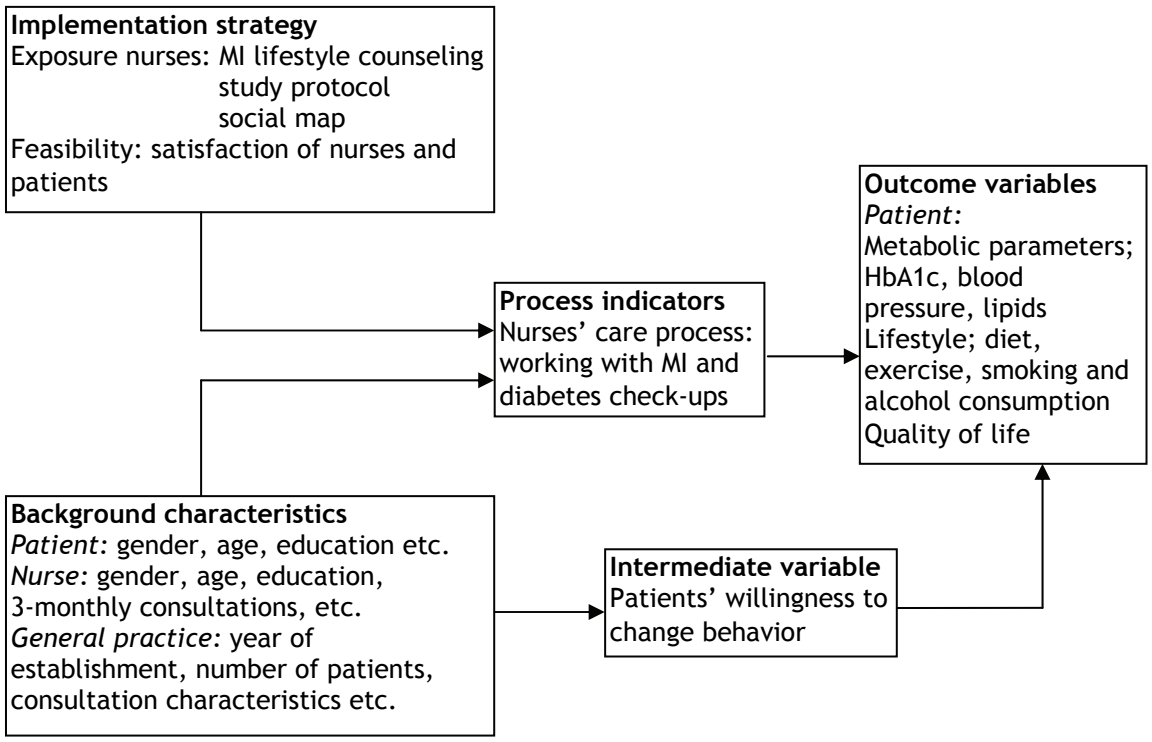


Table 1. Effect evaluation: outcome variables and instruments used to measure them

Outcome variables	Dutch guideline norms	Instruments
Care process		
Effects of MI	-	Record keeping
Results of diabetes check-ups	-	Medical files
Metabolic parameters		
HbA1c	< 7%	Medical files
Blood pressure	< 140 mm Hg	Medical files
Lipids: LDL	< 2.5 mmol/L	Medical files
Total cholesterol	< 4.5 mmol/L	Medical files
Lifestyle		Validated questionnaire,
Diet: Fruit and vegetables	2 pieces fruit (200 g or more) and 200 g vegetables or more	8 items[39]
Fat consumption	Total fat < 35 energy percent Saturated fat < 10 energy percent	Validated questionnaire, 35 items[38]
Physical activity	30 min for 5 days/week	Questionnaire, modified Dutch version of the CHAMPS, unvalidated, 15 items[40,41] Personal activity meter with diary for 7 days
Smoking	No smoking	Validated questionnaire, 2 items[37]
Alcohol consumption	Men: maximum 2 glasses Women: maximum 1 glass	Validated questionnaire, 2 items[42]
Quality of life	-	Validated questionnaires, EQ-5D 5 items and VAS 1 item[43,44]
Patients' willingness to change behavior	-	Questionnaire

The outcome measures will be the care process, the patients' metabolic parameters HbA1c, blood pressure, lipids (low-density lipoprotein (LDL) and total cholesterol), lifestyle (diet, exercise, smoking, and alcohol consumption), health-related quality of life, and the patients' willingness to change their behavior.

Working with MI and diabetes check-ups carried out by primary care nurses will provide the two measures of the care process. Data about the degree to which the nurses work according to the MI principles will be obtained from the record keeping, and data from medical files will help us gain insight into the diabetes check-ups. The metabolic parameters will be obtained from medical files. The current state of the art in measuring lifestyle changes is a multi-method approach that combines feasible self-reporting and reasonably objective measures. The patients will also report specific behaviors relating to smoking[37],

saturated fat intake[38], fruit and vegetable consumption[39], physical activity[40,41] and alcohol use[42] by means of validated self-reported questionnaires. We will use an objective measurement, the personal activity meter (PAM), with a diary for recording physical activity for 7 days. A combination of subjective and objective reporting will be chosen to get insight into the amount of exercise. A self-reported questionnaire will be used to measure the health-related quality of life[43,44] and the patients' willingness to change their behavior. This willingness to change will be determined on the basis of answers to questions about the importance and the confidence to change. Other factors that will be recorded include background characteristics about the patient (sex, education, etc.), the nurse (sex, age, etc.) and the general practice (year of establishment, consultation characteristics, etc.).

Timing of measurements

Information will be collected before intervention starts (T0), as well as at the end of the trial 14 months later (T1) for the intervention and control arms:

- At T0 (baseline), the research team will collect data from medical files, such as HbA1c concentration, blood pressure, and lipid values. Eligible patients will receive the first questionnaire from our research team (with an invitation letter from the GP) to assess their lifestyle and quality of life. Primary care nurses will instruct participating patients to carry a personal activity meter for 1 week, and to keep a diary, noting his/her physical activity for that week.
- At T1, the second and final questionnaire, PAM and diary will be sent to the patient's home address. The primary care nurse will collect data from medical files regarding medical parameters from the most recent patient contact.

The questionnaires, personal activity meters, diaries, and recording forms for medical file research are to be sent to the research team in a postage-paid envelope after completion.

All these materials will carry a unique patient number, and the patient number will be related to the involved general practice number.

Data analysis

Dichotomization of the patient outcomes. The HbA1c concentration must be less than 7%; blood pressure, less than 140 mm Hg; the LDL, less than 2.5 mmol/L; and the total cholesterol, less than 4.5 mmol/L [18]. Patients must eat two pieces

of fruit and 200 g of vegetables per day, must exercise 30 minutes a day at least 5 days a week, must consume less than 10 energy percent in saturated fat, must not smoke, and must consume no alcohol or only a moderate amount[45]. Descriptive statistics will be used to summarize factors of general practice, primary care nurse and patient factors for the two study arms and to check for comparability in baseline variables between the control arm and the intervention arm. We will use logistic regression techniques accounting for two levels (patient and practice) to statistically compare the intervention and control arms. The baseline measurement will be used in the model as a co-variant. Since different staff members in one practice are involved in the treatment of the diabetes nowadays (care given at practice level), we will have to choose the level of the practice. Exploratory analyses are also planned to examine the effect of explanatory factors (e.g., sociodemographic factors) on the outcome.

Process evaluation

The purpose of the process evaluation will be to establish the actual exposure and to investigate the feasibility of the implementation strategy. The research question is, "To what extent do primary care nurses take part in the implementation strategy, and what do the nurses and patients think of this strategy?"

Variables and measurements

To establish exposure, we will measure the degree of application of the training program. Each nurse will be instructed to record 8 to 10 diabetes consultations before and after the trial to determine their actual MI usage. Data about the primary care nurses' actual exposure to the other components of the implementation strategy (making a diabetes protocol and social map) will be established in the training.

At the end of the study, the nurses will receive a questionnaire about the feasibility of the implementation strategy. This questionnaire consists of questions about their experience with the implementation strategy, such as, "Do you think the MILD project would be useful to other nurses?" and "Looking back, would you participate in the MILD project again?" Patients will also be asked to fill in a questionnaire about their satisfaction with the diabetes consultations with questions such as, "What did you think of the diabetes

consultations last year?" For a more detailed overview of the process measures and instruments, see figure 2 and table 2. This process evaluation can shed light on obstacles and facilitators that can be used for broader implementation.

Table 2. Process evaluation: the measures and the instruments used to determine their effects

Measures	Instruments
Exposure	
Lifestyle counseling with MI	8–10 Video recording, which will be scores with the checklist "BECCI"[46]
Diabetes protocol	-
Social map	-
Feasibility	
Nurses' perception and experience of the implementation strategy	Questionnaire
Patients' opinion of diabetes consultations	Questionnaire

Data analysis

We will explore the influences on the model introduced by differences in the primary care nurses' accurate performance of MI. Video recordings of diabetes consultations in the intervention and control arms will be scored with the existing checklist, the BECCI, to determine the extent to which the MI technique was implemented[46]. Descriptive statistics will be used to summarize the patients' opinions of the diabetes consultations and the nurses' opinions of the feasibility of the implementation strategy.

Economic evaluation

The economic evaluation will estimate the cost-effectiveness of the MILD implementation intervention. The research question will be, "What is the incremental cost-effectiveness of our implementation strategy compared to usual care given by a primary care nurse?"

Measurements and variables

Cost-effectiveness analysis will be done from a healthcare perspective with a lifetime horizon because changes in glycemic control affect long-term complication risks. In a previous study, we show that adherence to the diabetes guidelines is cost-effective from a perspective of a lifetime horizon[47,48]. The costs of the implementation strategy will be included, such as costs of changes

in the diabetes organization, training the professionals in MI, and extra telephone calls with the patients as well as the major patient-related cost items (number and type of appointments and treatment). The effects measured in the model evaluation will be the effects on the HbA1c concentration as the primary outcome measure, and on exercise levels, dietary habits, cardiovascular risk score, and alcohol consumption as process indicators.

Data analysis

The economic evaluation will be a cost-effectiveness study. The cost will be balanced against the effect measures in a standardized model approach. In this study, policy cost-effectiveness will also be analyzed in a Mason model that includes the following sections[49]:

1. Developmental costs of the implementation
2. Training of primary care nurses
3. Activities of health professionals and patients during the intervention period, e.g., clinic visits and telephone contacts
4. Costs of treatment, e.g., for use of health care services, drugs, specialist care, and complications.

Training and material costs will be based on real costs, and national guidelines will be used[50] to calculate the cost of professional activities. The actual number of patients in the intervention arm will be used to calculate the cost of the intervention activities per patient. The volume of the patient activities will be registered in the patient files, while patients will be asked to record activities outside the general practice in a diary. We expect these costs to be less than 20 euros per treated patient. On the basis of earlier research, we know that this amount of money is certainly cost-effective[51,52].

Time frame

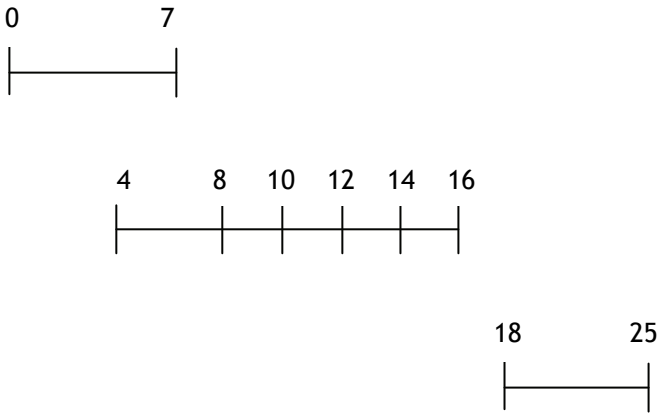
We plan to randomize all general practices that declare their willingness to participate in this study. The baseline data collection will take place at the beginning of the study during the 1st 7 months (figure 3). The training will start in month 4, and the follow-up meeting will be organized in month 12. There will be three telephone follow-ups to inquire about the nurses' development of health counseling in months 10, 14, and 16. Follow-up data collection will take place in months 18–25 inclusive. The time scheduled for the trial is 25 months.

Figure 3. Time frame for the Motivational Interviewing to Change the Lifestyle of Patients with Type 2 Diabetes Study. All numbers refer to months.

Baseline/ pre-measurement
- Video recordings PN
- Medical files research team
- Questionnaires and personality activity meter for patients

Training
- Training sessions (months 4-8)
- Follow-up meeting (month 12)
- Telephone follow-ups (months 10, 14, 16)

Post-measurement
- Video recordings for nurses
- Medical files for research team
- Questionnaires and personal activity meter for patients
- Process evaluation questionnaire for nurses



Discussion

The design of a cluster, randomized, controlled trial is optimal from the methodological perspective, and it could shed light on the effectiveness of the individual ingredients of this multifaceted intervention. The implementation strategy that will be evaluated in this trial is characterized by its innovative aspects. There is a wide range of interventions aimed at improving the provision of diabetes care in primary care, but not much is known yet on how to implement and integrate different intervention strategies effectively within day-to-day care in general practice[53,54]. If this intervention proves to be effective and cost-effective, its implementation will be considered and anticipated.

Selection bias is a widespread problem in cluster randomized trials[55]. Some of the biases associated with the use of cluster designs can be avoided with careful attention to the design. Identifying patients before randomizing the practices will be impossible in our study design, so we will use an independent recruiter to recruit the participants. In this way, we will take adequate precautions to guard against threats to the internal validity of the design suggested by Torgerson[56]. It is important to use a randomized design in the study because there will inevitably be other initiatives relating to diabetes that will begin during our study period, and because we will need to check for unknown effect

mediators and moderators. We choose to involve many practices with relatively few patients instead of a few practices with relatively many patients for two reasons. First, more practices will increase the chance of successful implementation in more practices, and will also decrease cluster contamination. We will get also more information about the conditions necessary for implementing our strategy in a large group of practices[57,58].

We assume that getting the practice motivated for structured care will not be very difficult, if they can get some support from us for making their schedules. We also assume that it will be easy to motivate the primary care nurse to use the MI tool because an effective tool for discussing diet and exercise is currently not available in general practice. However, the nurses will have to be supported in their motivation to participate, especially in the long run. Some suggestions from the literature that we have already elaborated on in our intervention strategy are MI training followed by a follow-up meeting, an instruction chart with counseling techniques, a record keeping system for consultation data and behavioral change, and regular telephone follow-ups to the primary care nurses. These items can be helpful in maintaining motivation, as well as getting feedback about the results[59].

In contrast to these assumes, we think that it is very difficult to receive the records of the nurses in order to establish the actual usage of MI. We will provide effort to get the records of all primary care nurses, because these records are very useful.

Furthermore, we expect that there will be more effects on lifestyle outcome measures than on metabolic parameters because a lifestyle change must occur before we can measure an effect on metabolic parameters. We expect the metabolic parameters to have stronger long-term effects.

Although we originally intended to use more objective measures for the outcome measurements of the effect evaluation, logistic and financial conditions often preclude this. A biomarker for fruit and vegetables, such as carotene measurement, is expensive. There is no simple biomarker available for alcohol. The influence of information bias resulting from subjective self-reports can be reduced in the data analysis by taking the use of pre-intervention scores (which have the same information bias) into account. We will make use of practicable objective measurements of physical activity. Personal activity meters are known not to register all activities with accuracy, and the level of activity can vary from week to week, but we have chosen to combine subjective

and objective data to get better insight into the amount of exercise. There are a great many different actometers in circulation. We have chosen an accelerometer, which is more accurate than the pedometer that counts the number of steps walked in a day[60,61].

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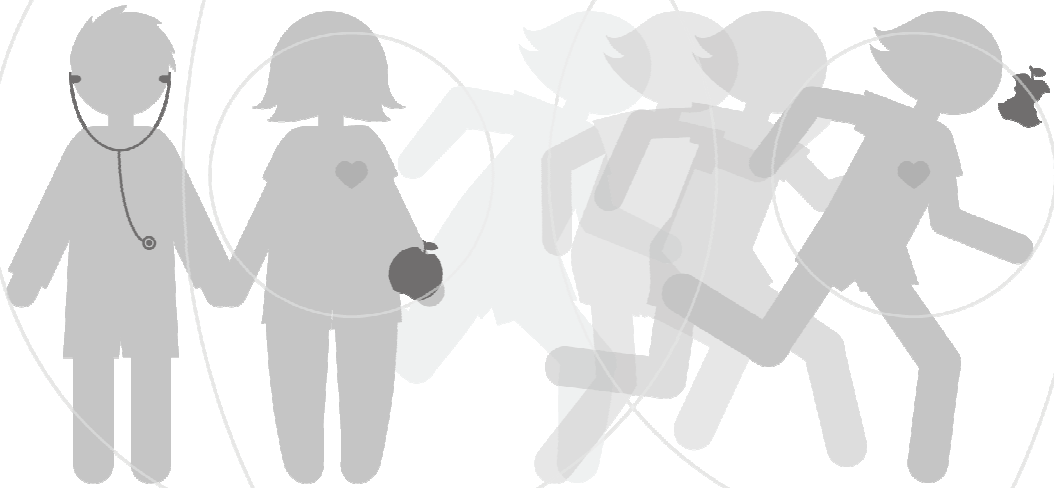
Chapter 5

No identifiable Hb1Ac or lifestyle change after a comprehensive diabetes programme including motivational interviewing: a cluster randomised trial

Renate Jansink
Jozé Braspenning
Ellen Keizer
Trudy van der Weijden
Glyn Elwyn
Richard Grol



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Abstract

Objective. To study the effectiveness of a comprehensive diabetes programme in general practice that integrates patient-centred lifestyle counselling into structured diabetes care.

Design and setting. Cluster randomised trial in general practices.

Intervention Nurse-led structured diabetes care with a protocol, record keeping, reminders, and feedback, plus training in motivational interviewing and agenda setting.

Subjects. Primary care nurses in 58 general practices and their 940 type 2 diabetes patients with an HbA1c concentration above 7%, and a body mass index (BMI) above 25 kg/m^2.

Main outcome measures. HbA1c, diet and physical activity (medical records and patient questionnaires).

Results. Multilevel linear and logistic regression analyses adjusted for baseline outcomes showed that despite active nurse participation in the intervention, the comprehensive programme was no more effective than usual care after 14 months, as shown by HbA1c levels (difference between groups= 0.13; CI: -0.8 -0.35) and diet (fat (difference between groups= 0.19; CI: -0.82-1.21); vegetables (difference between groups= 0.10; CI: -0.21-0.41); fruit (difference between groups= -0.02; CI: -0.26-0.22)), and physical activity (difference between groups= -1.15; CI: -12.26-9.97), or any of the other measures of clinical parameters, patient's readiness to change or quality of life.

Conclusion. A comprehensive programme that integrated lifestyle counselling based on motivational interviewing principles into structured diabetes care did not alter HbA1c or the lifestyle related to diet and physical activity. We thus question the impact of motivational interviewing in terms of its ability to improve routine diabetes care in general practice.

Introduction

The prevalence of diabetes is rapidly increasing, due to ageing and changes in lifestyle[1]. The situation is exacerbated by the lack of adherence to the diabetes type 2 recommendations on diet and exercise[2,3]. In many countries, such as the Netherlands, diabetes care has now largely been delegated to primary care nurses. They have to make patients aware of their unhealthy lifestyle and motivate them to change their lifestyle. The complexity of lifestyle change requires a shift from simple advice giving, as described in most diabetes guidelines, to a more patient-centred counselling-based approach[4,5]. Motivational interviewing (MI) has emerged as a promising counselling model for health promotion and disease management, even in brief encounters in general practice[6]. It is a patient-centred method, which makes the patient and professionals jointly responsible for deciding on the treatment plan[7]. Studies have shown that this method can contribute to lifestyle change, such as reducing energy intake from fat, increasing fruit and vegetable consumption[8], increasing physical activity, and lowering weight[9]. Beneficial effects on body mass index, cholesterol, and blood pressure have also been noted[6]. However, most research conducted on this topic has examined the effect of MI on a single behaviour, whereas diabetes is a complex and chronic illness that requires multiple behavioural changes. Compliance to lifestyle advice decreases when several lifestyle behaviours are targeted at the same time[10]. An effective intervention including training nurses in MI will therefore probably not be sufficient, with structured care programmes being needed[11]. Therefore, we developed a comprehensive programme with a focus on training in lifestyle counselling based on MI.

In our study, we assessed the effect of this comprehensive diabetes programme on clinical parameters, lifestyle, patients' readiness to change lifestyle and quality of life. We also evaluated the participation of nurses in the intervention programme.

Material and methods

Study design and study population

General practices were recruited to take part in a cluster randomised trial in the south-eastern part of the Netherlands, from May 2006 to February 2007. Invitation letters were send with an estimated number of 2500 practices. The 70 practices who volunteered were visited by the first author to explain the study activities. Before randomisation 12 practice withdrew for practical reasons or anticipated disappointment not to be allocated to the intervention group. Randomisation was performed at the level of the general practice (stratified by practice size and level of urbanisation). Patients with type 2 diabetes were eligible to participate when they were younger than 80 years, had an HbA1c above 7%, and a body mass index (BMI) above 25 kg/m^2. Exclusion criteria were complex comorbidity and treatment in hospital. The research team made a list of all eligible patients by screening the medical files before allocation. Patients were invited by letter and signed an informed consent form.

Intervention

Nurses in the intervention group received a comprehensive programme[12] consisting of (a) training in lifestyle counselling based on motivational interviewing[13]; (b) the introduction of tools for structuring diabetes care, such as training in agenda setting, a local diabetes protocol based on the national guidelines[14] that was discussed with them, and a social map for lifestyle support; (c) instruction on record keeping to integrate lifestyle counselling into general practice; and (d) introduction of tools to sustain improvements including an instruction chart (reminder)[11], regular telephone follow-ups with the target patients, a help desk that also inquired pro-actively about the progress of diabetes management, and a follow-up meeting for the nurses (figure 1).

Interventions (a) and (b) took place during the training sessions, which consisted of four half-day training sessions (total 16 hours) spread over the first half year. Nurses attended these sessions in groups of 5-8 outside the practice. The other activities started after these training sessions (after six months) and lasted till the post-measurement after 14 months. The record-keeping and the instruction chart were offered to nurses during the last training session. They received an oral and written explanation of the record-keeping and recommendations for regular telephone follow-ups for diabetes patients. During the intervention

period the research team called the primary care nurse once a quarter (three times) to enquire about their development of health counselling. The nurses could call the research team for information any time. About four months after the last training session, the nurses were invited to participate in a follow-up meeting to discuss the barriers in practice and to receive feedback about their own video-recording. What went right, and what could be better? The usual care nurses were advised to administer care consistent with current diabetes guidelines.

Figure 1. The several interventions of the comprehensive diabetes programme

Training in motivational interviewing (4 half-days, spread equally over 6 months)

1. **Training** primary care nurses in the principles of **motivational interviewing (MI)** in order to encourage patients with diabetes to adhere to lifestyle guidelines. The following components were discussed:
   - *Building motivation for change: importance and confidence*
   - *Asking open questions, listening reflectively, affirming, summarizing, and eliciting change*
   - *Expressing empathy, developing discretion, rolling with resistance, and supporting self-efficacy.*

Structured diabetes care

2. Training in **agenda setting** to make consultations more structured and to draw up concrete appointments.
3. Tailoring a **diabetes protocol** to the local setting.
4. Introducing a **social map** for lifestyle change to primary care nurses. The map provides an overview of all available organizations and their treatment programmes to help patients choose, for example, the right sport school or physiotherapist.

Lifestyle counselling embedded in usual care

5. **Record keeping** of consultation data and changes in the behaviour of patients, conducted by primary care nurses.

Maintained motivational interviewing

Reminder

6. An **instruction chart** with counselling techniques, as a reminder for nurses to encourage maintenance of the MI techniques used to help patients change.

Follow-up

7. Recommendations for **regular telephone follow-ups** for diabetes patients, which are monthly in the first 6 months and then probably decrease.
8. A **help desk**: the research team will call the primary care nurse three times to inquire about their development of health counselling and nurses can call the research team for information.
9. A **follow-up meeting** to receive feedback about their own video recordings.

Measures and data collection

The primary outcomes were HbA1c and reported changes in lifestyle related to diet and physical activity. Data on diabetes outcome measures (HbA1c, blood pressure, cholesterol, BMI) and process indicators (see table 4) were extracted from medical records. The research team identified all the eligible patients with an HbA1c of 7% or more. Only data of those patients who had given informed consent were collected by extracting the information manually from the electronic medical records. In case of more measurements per patients within the 12 months' retrospective window, the most recent value was collected. Patient questionnaires were used to collect data on alcohol, fat, vegetables, and fruit consumption over the past month[15-17]. Physical activity was measured by asking patients to describe a typical week during the last month[18]. Physical activity was also reported more objectively based on a personal activity meter (PAM) and a diary (same week). For each lifestyle aspect the importance of and confidence in changing was rated on a five-point Likert scale; each patient's readiness to change was defined by multiplying the two items[13]. Quality of life was assessed using the Euroqol[19]. Data were gathered at baseline, and after 14 months. In the Dutch diabetes guidelines it is stated that diabetes patients should be seen once a quarter and the HbA1c should be measured yearly. For practical reasons (e.g. holidays, forgotten) it can be difficult to perform the yearly visit. We therefore took a time frame of 14 months.
The exposure of nurses to MI, agenda setting, diabetes protocols, and social maps was measured by recording their attendance at the different training sessions on these subjects. Furthermore, we asked nurses if they used the instruction chart, and we recorded the number of nurses who received three telephone follow-ups from the research team, as well as their participation in the follow-up meeting.

Sample size

With the intervention used, we expected 50% of the eligible patients to achieve an Hba1c below 7%[12]. Based on an alpha of 5% and a beta of 80% a random sample of 30 general practices with five patients each was needed, taking into account an intra-cluster correlation of 0.05 (patients in practices). For lifestyle we expected a 5% change in usual care, and an extra 10% change due to the intervention[12]. Without changing the other assumptions, a total of 68 practices with 10 patients were needed to detect the expected difference in lifestyle

between the intervention and usual care groups. We thus planned to recruit 70 general practices with 700 patients, allowing for some loss.

Statistical analysis

Means and standard deviations, and percentages where appropriate, were used to summarise the characteristics of the general practices, nurses, and patients. Comparisons between the intervention and usual care arms were adjusted for clustering within practices. Continuous outcome measures (clinical outcomes, reported aspects of lifestyle, and quality of life) were analysed with multilevel linear regression in SPSS. The HbA1c was added as a continuous measure in the statistical model to avoid loss of power. Binary outcome measures (patients' readiness to change and diabetes process indicators) were analysed using multilevel logistic regression in SAS. In these analyses baseline measures were defined as a separate predictor in the model. We also adjusted the models for baseline characteristics (from practices, nurses, or patients) that differed significantly between the intervention and usual care groups.

Results

Study population

Figure 2 presents the number of general practices and participants in this trial.

Figure 2. Flow diagram of general practices and patients at different stages (enrolment, allocation, baseline measurement, follow-up, and analysis) of the trial

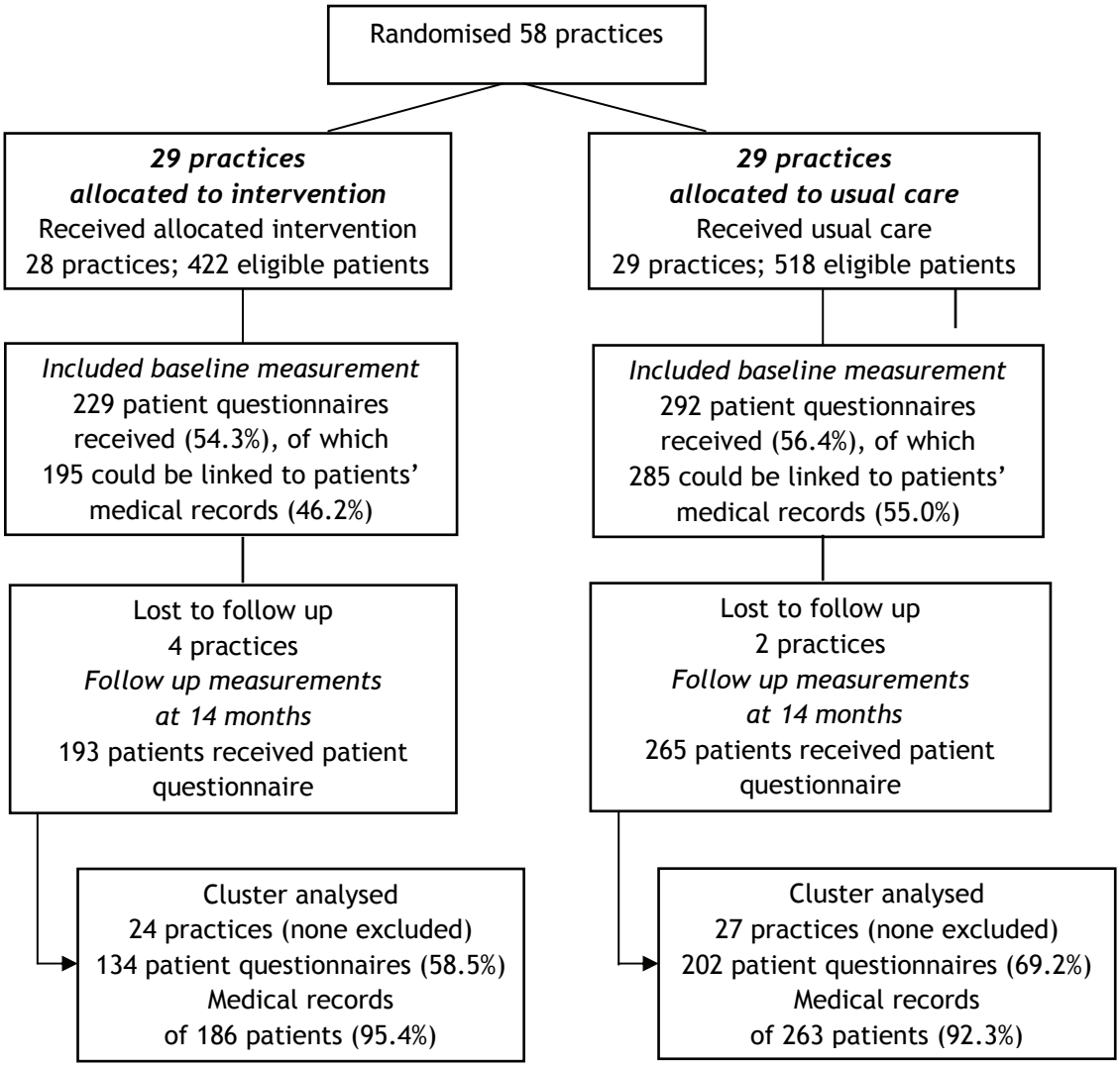

Table 1 presents the baseline characteristics of the general practices, nurses, patients and the baseline values regarding outcome measures, lifestyle, and quality of life.

Table 1. Baseline characteristics of general practices, primary care nurses, patients and baseline values of measures

	Intervention		Usual care	
		s.d.		s.d
General practices (n=53)[a]	25		28	
Mean number of patients in general practice[b]	4566	2703.8	5657	4153.3
Mean number of patients with type 2 diabetes in general practice	195	109.6	202	119.4
Mean fte[c] primary care nurses in general practice	0.6	0.3	0.8	0.6
Primary care nurses (n=53)[d]	25		28	
Mean age in years	40.7	7.8	44.4	6.6
Number of men/number of women	2 / 23		1 / 27	
Mean years of experience with diabetes consultations	3.6	2.1	3.6	2.1
% nurses who were formerly practice assistants	48.0		53.6	
Mean years of experience as practice assistant	4.3	5.3	8.4	8.8
Patients (n=521)	229		292	
% men	55.9		54.0	
Mean age in years	64.1	8.9	63.9	9.8
Mean duration of diabetes in years	7.5	6.0	7.8	5.8
Baseline (n=336)	134		202	
Outcome measures				
HbA1c, %	7.8	0.9	7.7	0.7
Systolic blood pressure, mm Hg	144.4	20.3	140.7	18.0
Diastolic blood pressure, mm Hg	81.9	10.6	79.9	9.9
LDL, mmol/l	2.8	1.0	2.5	0.8
Total cholesterol, mmol/l	4.7	1.0	4.5	1.0
BMI, kg/m^2	30.7	4.2	30.7	4.2
Lifestyle				
Alcohol, units/day[e]	2.3	1.0	2.2	1.1
Fat score, g/day	14.1	4.5	14.5	4.9
Vegetables, tablespoons/day	2.9	1.6	3.0	1.5
Fruit, pieces/day	1.9	1.1	1.8	1.1
Physical activity, minutes/day	64.8	66.1	58.6	45.1
Pamscore[f]	19.2	8.5	21.2	8.0
Low activity, minutes/day	73.2	40.3	77.0	37.0
Medium activity, minutes/day	21.1	23.4	23.4	23.8
High activity, minutes/day	0.3	0.8	0.7	3.3
Diary activity, minutes/day	129.9	77.4	153.9	103.4
Quality of life				
VAS score	74.1	16.2	73.1	13.5

[a] Four general practices withdrew from the study before the nurse had completed the questionnaire about the baseline characteristics
[b] s.d.: standard deviation
[c] fte: full time equivalent
[d] In six practices two nurse were employed. In such cases we calculated the mean of the nurse characteristics, because the mean values were used in follow-up analyses.
[e] Only people who reported alcohol consumption
[f] Pam score= Personal activity meter score

Follow-up analyses

Based on the medical records of the dropouts at baseline we learned that follow-up was somewhat higher among older patients (63.8 vs. 61.4 years), and patients with a lower BMI (30.8 vs. 32.4) and a lower HbA1c (7.8% vs. 8.0%). At follow-up after 14 months we lost very little information from the medical records, but again not all patient questionnaires were returned (see figure 2). The follow-up was not affected by age or BMI, but the HbA1c of the non-responders was slightly higher (0.2%) than that of responders.

Diabetes care

Table 2 shows that compared with usual care the comprehensive programme did not result in statistically significant improvements in the diabetes outcome measures (HbA1c, blood pressure, cholesterol, BMI). However, the small changes in cholesterol outcomes (LDL and total) had a $p<0.10$. Post measurement showed that in the intervention group 34.5% reached the HbA1c target value (below 7%) compared with 34.0% in the usual care group (OR=1.17, 95% CI=0.74-1.85, p-value=0.49). The number of people with an HbA1c above 8.5% decreased in the intervention group from 16.5% to 9.8% and in the usual care group form 11.9% to 9.8% (OR=1.01, 95% CI=0.42-2.39, p-value=0.99).

The comprehensive diabetes programme was no more effective than usual care in terms of the reported consumption of alcohol, fat, vegetables and fruit, or physical activity. Physical activity showed different outcomes when measured by questionnaire, personal activity meter, or diary, but none of these outcomes differed between intervention and usual care. The intervention did not increase or decrease quality of life compared to usual care.

Table 2. Effect of comprehensive diabetes programme on diabetes outcome measures, lifestyle and quality of life after 14 months follow-up[a]

	Intervention			Usual care			Difference between groups[b]	95% CI	P-value
	M	s.d.	n	M	s.d.	n			
Outcome measures									
HbA1c, %	7.3	0.7	129	7.4	1.0	197	0.13	-0.08-0.35	0.221
Systolic blood pressure, mm Hg	141.5	17.0	120	137.8	15.8	185	-1.98	-5.63-1.67	0.279
Diastolic blood pressure, mm Hg	79.5	8.4	120	77.6	9.2	120	-1.17	-3.41-1.07	0.294
LDL, mmol/l	2.6	0.8	106	2.4	0.6	178	-0.15	-0.32- -0.02	0.081
Total cholesterol, mmol/l	4.5	1.0	122	4.2	0.8	186	-0.21	-0.41-0.00	0.051
BMI, kg/m^2	30.2	4.0	106	30.5	4.6	179	0.36	-0.19-0.90	0.198
Lifestyle									
Alcohol, units/day[c]	2.2	1.0	58	2.2	1.1	95	0.04	-0.14-0.23	0.647
Fat score, g/day	13.9	5.4	105	14.2	6.1	163	0.19	-0.82-1.21	0.708
Vegetables, tablespoons/day	3.1	1.6	102	3.1	1.5	165	0.10	-0.21-0.41	0.518
Fruit, pieces/day	1.8	1.1	119	1.7	1.2	173	-0.02	-0.26-0.22	0.884
Physical activity, minutes/day	62.8	69.6	124	59.1	51.3	171	-1.15	-12.26-9.97	0.839
Pam score[d]									
Low activity, minutes/day	78.3	40.3	78	78.8	39.8	120	-2.70	-10.52-5.14	0.498
Medium activity, minutes/day	22.5	27.0	78	22.6	20.2	120	-1.46	-6.80-3.89	0.592
High activity, minutes/day	0.4	0.9	78	1.0	6.5	120	0.18	-0.65-1.01	0.669
Diary activity, minutes/day	152.9	97.6	84	157.4	89.0	128	-19.36	-39.97-1.26	0.066
Quality of life									
VAS score	75.3	16.2	111	73.5	13.6	171	-1.27	-4.50-1.97	0.441

[a] Adjusted for baseline measures, nurses' years of experience, and cluster effects
[b] Difference between intervention and usual care group (reference group)
[c] Only people who reported alcohol consumption
[d] Pam score= Personal activity meter score

Table 3 indicates that the intervention did not change any aspect of patients' readiness to change their lifestyle. The number of participants who themselves reported not meeting the norm was lower than expected in a group with a BMI above 25 kg/m^2.

Table 3. Effect of comprehensive diabetes programme on patients' readiness to change lifestyle[a] after 14 months follow-up[b]

	Intervention			Usual care			B	95% CI	P-value
	M	s.d.	n	M	s.d.	n			
Alcohol, units/week[c]	12.8	4.1	11	10.5	3.6	18	-1.03	-3.93-1.86	0.471
Fat, g/day	14.8	6.0	30	13.0	3.9	43	0.21	-3.19-3.60	0.901
Vegetables, g/day	12.5	5.1	89	13.7	4.5	150	0.74	-0.47-1.96	0.228
Fruit, pieces/day	12.5	4.4	71	11.9	4.1	116	-0.38	-1.82-1.05	0.597
Physical activity, min/day	11.7	5.4	63	11.1	4.1	126	-0.48	-2.13-1.17	0.563

[a] Only for patients who did not reach the norm for lifestyle; range 1–25.
[b] Adjusted for baseline measures and nurses' years of experience
[c] Only people who reported alcohol consumption

The findings on diabetes process indicators revealed that the number of patients receiving lifestyle advice neither increased nor decreased as a result of the comprehensive diabetes programme (table 4). The probability of annual checks on HbA1c, blood pressure, and LDL increased, but only significantly for blood pressure. However, the high adherence rates at baseline in both the intervention and usual care group suggested that this significant finding is not clinically relevant.

Nurses in the intervention actively participated in the programme, with 93% attending at least three out of four MI training sessions. The social maps and local diabetes protocols were discussed by 74% of the nurses. All practices received the three quarterly telephone follow-ups from the research team after training. During these conversations, nurses indicated that the instruction chart was very useful. Most of them had the chart on their desk and used it during or after consultations. Although the nurses requested an MI follow-up meeting, participation was low (37%).

Table 4. Effect of comprehensive diabetes programme on diabetes process indicators after 14 months follow-up[a]

	Number of patients (%)		Odds ratio	95% CI	P-value
	Intervention n=186	Usual care n=263			
Dietary advice	104 (56)	119 (45)	0.96	0.86-1.06	0.838
Physical activity advice	106 (57)	116 (44)	0.96	0.87-1.06	0.984
HbA1c checked	182 (99)	251 (95)	2.13	0.60-7.53	0.239
Blood pressure checked	185 (100)	245 (93)	13.59	1.79-103.37	0.01
Total cholesterol checked	174 (94)	242 (92)	0.99	0.94-1.04	0.554
LDL cholesterol checked	169 (91)	239 (91)	2.25	1.01-5.00	0.838
Creatinine (serum) checked	174 (94)	242 (92)	1.02	0.96-1.07	0.322
Microalbuminuria checked	163 (88)	223 (85)	0.98	0.93-1.04	0.931
Eye examination[b]	61 (33)	106 (40)	1.01	0.96-1.06	0.717
Foot examination	131 (70)	205 (78)	0.98	0.94-1.02	0.101
BMI determined	166 (89)	230 (87)	0.97	0.91-1.04	0.832
Cholesterol lowering medication	80 (43)	93 (36)	0.97	0.88-1.07	0.955

[a] Adjusted for baseline measures and nurses' years of experience
[b] In general once in 24 months, but we recorded eye examinations in the last 12 months

Discussion

Statement of principal findings

The comprehensive diabetes programme had no effect on HbA1c or reported aspects of lifestyle nor on the other diabetes outcome measures or quality of life. Patients with type 2 diabetes were no more ready to change lifestyle in the intervention practices than in usual care, and the adherence of nurses to guidelines for process measures showed no relevant improvement, despite their active participation in the training programme.

Strengths and limitations of the study

Strengths include the cluster RCT design, and the variety of measures (outcome and process, subjective and objective). As 70 out of 2500 practices participated voluntarily, it can be assumed that only practices that were enthusiastic about improving diabetes care by using MI were recruited. This could have affected the study results. However, improvement was not shown in the intervention or in the control group. A limitation of the study is the loss to follow-up in the lifestyle measures from the patient questionnaire. At baseline and follow-up we lost participants with a relatively higher HbA1c than those who remained within the study, which narrowed the room for improvement in HbA1c. We also noticed that the proportion of measurements differed between the intervention and

usual care group. Although, we formulated strict inclusion criteria and performed randomisation, it is possible that the population in the intervention and usual care group differed on variables beyond our set of measurements. Another limitation was the underpowered nature of the patient questionnaires. However, based on the difference between groups, confidence intervals and p-values in table 2, we can assume that a larger sample size would not have led to any significant changes either. The follow-up period was 14 months. It is theoretically possible that the effect can only be seen in the long term. But this contradicts other studies that showed an effect of MI directly after its introduction[6,20].

Comparison with existing literature

The comprehensive diabetes programme was based on elements that had proven to be effective such as structured diabetes management[11] and motivational interviewing[6,8,9]. Previous research has reported that for patients with type 2 diabetes the use of MI can improve glucose control, dietary changes, smoking, weight, physical activity, motivation for lifestyle change, and adherence to diabetes guidelines[6,8,9,21]. Knowing that dietary advice and physical activity are associated with a lower HbA1c[22,23], we would have expected our comprehensive diabetes programme to have an effect on HbA1c and lifestyle. However, recently more studies have questioned the effectiveness of MI in terms of clinical outcomes, lifestyle, quality of life, and self-efficacy for patients with type 1 and 2 diabetes or in cardiovascular risk management in routine care in general practice[24-27].

Explanation of the findings

There are several possible reasons why our trial failed to demonstrate any effectiveness of the comprehensive diabetes programme. A thought could be that Dutch diabetes care is already on a high level as the guideline was introduced in 1989, which makes further improvement difficult as could be shown by the mean HbA1c of 7.8% at baseline. Improvement on but eye examinations were recorded in the last 12 months. BMI, however, was certainly possible in the study population. Another explanation could be that the education of the nurses was of such level that lifestyle education was performed on almost the same level in both the intervention and control group, and the training programme hardly added value. Nurses in the Netherlands are trained

in a three- to four-year curriculum (middle or higher education) and afterwards they can specialise in primary care following a one- or two-year curriculum. Lifestyle counselling is part of the curriculum, but not specifically focused on motivational interviewing. The education is a prerequisite for effective lifestyle counselling, but no guarantee for reaching good outcomes. The lifestyle outcomes in the study showed that there could be improvement. We could consider the quality of our training programme itself, but there are no comparable data. It is only known that the four training sessions offered were sufficient[28]. As nurses themselves asked for an extra session, it can be concluded that more support was desirable. Perhaps training on the job can help to produce more effective lifestyle counselling[29].

As room for improvement was available and nurses in the intervention group were better equipped to perform lifestyle counselling, the study results could be explained by the study design itself. Some of its weaknesses have already been discussed, but there impact seems to be limited. Could it be that the time frame chosen was too short? Fourteen months after the intervention the post measurements took place, but not all of the patients were seen at the same time. An extra analysis on this subject showed that on average the measurements were performed in the midst of the time frame. It can be assumed that lifestyle changes take more time, but earlier studies have found MI effects after 3–4 months[6,30].

Explanations can also be found in our target population. MI was originally developed for substance abuse[13], requiring a single behavioural change, whereas diabetes is a complex chronic illness that requires multiple behavioural changes. MI may be less effective for multiple behavioural changes, despite the fact that our nurses were trained to set the agenda. In case of diabetes it may be better to organise a setting that is explicitly dedicated to MI. Separate MI sessions have been shown to be successful[31]. In our programme the counselling strategy was applied during regular nurse consultations. Or are we being naive? Targeting changes in biomedical parameters and lifestyle in an elderly population with type 2 diabetes is a battle involving a complicated social, psychological, and physiological web of related issues[32]. Our comprehensive diabetes programme may not have been nearly comprehensive enough.

Implications for future research on clinical practice

Our results indicate a need for further research on lifestyle counselling embedded in primary care and the assessment of factors influencing the use of such counselling strategies for a better understanding of the applicability of interventions in diabetes care. One approach may lie in the argument that the environment in which we live may be the driving force behind many of our less healthful lifestyle habits[33]. A health protection approach with a possible role for the polypill to reduce cardiovascular risk may be more effective than a motivational intervention[34-36]. Another direction can be an investment in acquiring knowledge on *personalised* lifestyle counselling. Is it possible to customise lifestyle counselling based on genetic or other information? In this case MI will be offered to those patients who will benefit most instead of being part of routine diabetes care. Nurses can focus energy into work for this group with potentially more fruitful results.

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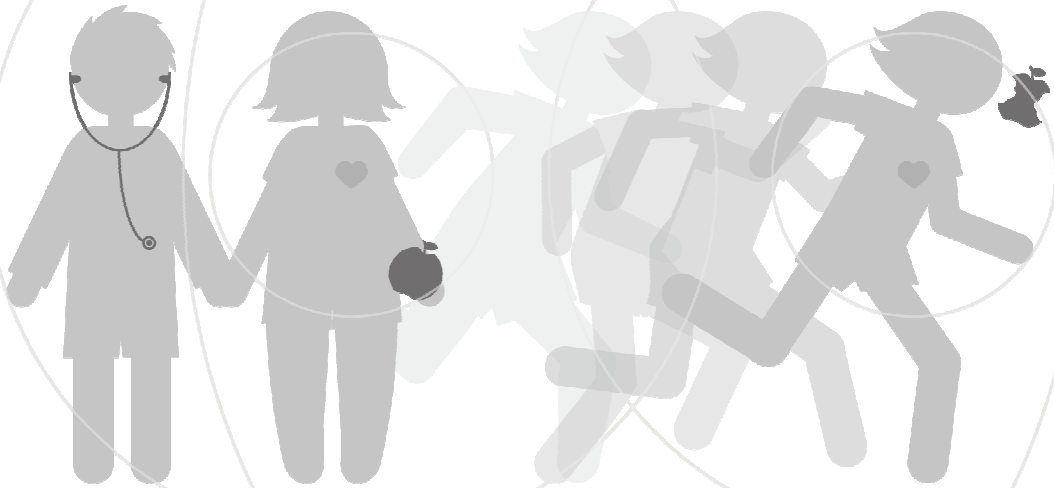
Chapter 6

Minimal improvement of nurses' motivational interviewing skills in routine diabetes care one year after training: a cluster randomized trial

Renate Jansink
Jozé Braspenning
Miranda Laurant
Ellen Keizer
Glyn Elwyn
Trudy van der Weijden
Richard Grol



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Abstract

Background. The effectiveness of nurse-led motivational interviewing (MI) in routine diabetes care in general practice is inconclusive. Knowledge about the extent to which nurses apply MI skills and the factors that affect the usage can help to understand the black box of this intervention. The current study compared MI skills of trained versus non-trained general practice nurses in diabetes consultations. The nurses participated in a cluster randomized trial in which a comprehensive program (including MI training) was tested on improving clinical parameters, lifestyle, patients' readiness to change lifestyle, and quality of life.

Methods. Fifty-eight general practices were randomly assigned to usual care (35 nurses) or the intervention (30 nurses). The ratings of applying 24 MI skills (primary outcome) were based on five consultation recordings per nurse at baseline and 14 months later. Two judges evaluated independently the MI skills and the consultation characteristics time, amount of nurse communication, amount of lifestyle discussion and patients' readiness to change. The effect of the training on the MI skills was analysed with a multilevel linear regression by comparing baseline and the one-year follow-up between the intervention with usual care group. The overall effect of the consultation characteristics on the MI skills was studied in a multilevel regression analyses.

Results. At one year follow up, it was demonstrated that the nurses improved on 2 of the 24 MI skills, namely, "inviting the patient to talk about behaviour change" (mean difference=0.39, p=0.009), and "assessing patients' confidence in changing their lifestyle" (mean difference=0.28, p=0.037). Consultation time and the amount of lifestyle discussion as well as the patients' readiness to change health behaviour was associated positively with applying MI skills.

Conclusions. The maintenance of the MI skills one year after the training program was minimal. The question is whether the success of MI to change unhealthy behaviour must be doubted, whether the technique is less suitable for patients with a complex chronic disease, such as diabetes mellitus, or that nurses have problems with the acquisition and maintenance of MI skills in daily practice. Overall, performing MI skills during consultation increases, if there is more time, more lifestyle discussion, and the patients show more readiness to change.

Background

The prevalence of type 2 diabetes is increasing mainly because of aging populations and changing lifestyles[1]. Medication, healthy diet, and physical activity can reduce blood pressure and concentrations of cholesterol and glycated hemoglobin (HbA1c), thereby lowering the risk of cardiovascular disease[2,3]. The professionals' adherence to the type 2 diabetes guidelines on diet and physical activity is low[4-6].

In many countries, such as the Netherlands, diabetes care is largely delegated to primary care nurses. They have to make patients aware of their unhealthy lifestyles and motivate them to change. Despite nurses' efforts to improve patients' lifestyle, healthy behaviour change remains difficult[7,8]. A promising technique for lifestyle counselling is motivational interviewing (MI), even during brief encounters for diabetes care in general practice[9].

MI is formally defined as a patient centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence[10]. Patient and professionals are jointly responsible for the treatment plan[11]. There are four general techniques of MI: (1) express empathy, (2) develop discrepancies, (3) roll with resistance, and (4) support self-efficacy (more information on MI is described in box 1). Five specific methods (open questions, affirming, reflecting, summarizing, and eliciting change talk) can be useful throughout the MI. Also agenda setting, scaling questions, and assessing importance and confidence in changing lifestyle can be used as techniques to support MI[12].

Psychological interventions such as MI can be taught to nurses and incorporated in traditional diabetes settings[13-17]. However, the effect of a brief MI intervention for diabetes patients in general practice is inconclusive. Some diabetes type 2 studies have found that MI is effective in lifestyle change[13,18-21], decreasing weight[18,22], and have beneficial effects on glucose target levels, body mass index, cholesterol, and blood pressure[9,19,20,23]. Other studies showed no effect of MI on HbA1c in general practices[9,13,15], and no effect on the lifestyle, clinical parameters, quality of life and self-efficacy[13,24,25].

Information about the extent to which nurses apply MI skills and the factors that affect usage can help to understand the mixed effect of MI in routine diabetes care, but studies that looked systematically into the maintenance of the various MI skills after training are lacking[9,26,27]. The current study reports a comparison on MI skills of trained versus non-trained nurses after a one-year follow-up. The nurses participated in a cluster randomized trial in which a comprehensive

program (including MI training) was tested on improving clinical parameters, lifestyle, patients' readiness to change lifestyle, and quality of life[28]. In addition, the influence of consultation characteristics on the utilization of MI skills will be described. The consultation characteristics under study were time, the amount of nurse communication, and the amount of lifestyle discussion during consultation as well as patients' readiness to change.

Box 1. Description of motivational interviewing

Motivational Interviewing (MI) is formally defined as "a client centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence" (Miller and Rollnick, 2002). The MI approach is distinguished from some other counselling models; it is not focused on 'I will change you', but on 'If you wish, I can help you change'. The four guiding principles of MI are (1) express empathy, (2) develop discrepancies, (3) roll with resistance, and (4) support self-efficacy.

1) "Expressing empathy involves providing clients with an atmosphere of respect and acceptance of their position. The technique used is reflective listening and this is generally considered the foundation of MI and is recommended throughout the counselling process." Example script: 'Sounds like working on getting exercise and keeping up your blood glucose is very demanding. I think it is natural to struggle sometimes. What is it like for you? Are there any obstacles that make it particularly difficult?'
2) "Develop discrepancies involves creating a 'gap' between the client's current behaviour and their broader goals, thus cultivating motivation for lifestyle change. When the client recognizes such discrepancies, a certain level of discontent arises that makes change more likely to occur. Discrepancies are developed by exploring the client's important life values and reviewing how their current behaviours affect their ideal lifestyle". Example script: 'So on the one hand you are not sticking with your exercise program, because it's hard to find time but on the other hand you think exercise would make you feel better and help manage your blood glucose level. It sounds like managing diabetes is pretty important to you. How do you think having a high BMI affect this overall? Where do the exercises fit in here?'
3) "Directly challenging resistance is counterproductive to lifestyle change because it typically results in the client defending their current state of affairs. Rather, resistance should be rolled with and channelled instead of confronted. Rolling with resistance invites the client to consider a new perspective versus having it imposed". Example script: 'It can be very frustrating to make all these changes, especially when it has becoming a habit and others giving you hard time. I think it is completely normal to want to go back to old habits when times are tough. May I tell you about some different options that have been worked well for others?'
4) "Self-efficacy, or one's confidence in the ability to change a specific behaviour under difficult circumstances, should be supported whenever possible because it is one of the best predictors of treatment outcome. Self-efficacy can be strengthened by affirming past success (i.e., reinforcement), presenting success stories of others (i.e., modelling), and expressing their belief in the client's potential to change". Example script: 'I see you have been keeping up your blood glucose level despite the difficulties adhering to your diet and exercises. It looks like you had a lot of initial success when you began making health changes. What worked so well for you then? Sometimes a setback can actually be a good thing.'

Methods

Study design and population

Nurses working in rural and urban general practices were recruited for a cluster randomized controlled trial in the south eastern part of the Netherlands. Randomization took place at the level of the 58 participating general practices (stratified by practice size and urbanization level) who employed a total of 65 nurses. Blinding was not possible for the nurses because the intervention group had to attend the training sessions. A complete study protocol has been described elsewhere[28].

Intervention

Nurses in the intervention group received a comprehensive program consisting of (a) training in lifestyle counselling based on MI; (b) introduction of tools for structuring diabetes care, such as training in agenda setting, a local diabetes protocol that was discussed with them, and a social map for lifestyle support; (c) instruction for record keeping to integrate lifestyle counselling into general practice; and (d) introduction of tools to sustain improvements including an instruction chart (reminder), regular telephone follow ups with the target patients, a helpdesk that inquired proactively about the diabetes management, and a follow up meeting for the nurses (box 2).

The training in MI techniques and the introduction of tools to structure diabetes care took place during the training sessions, which consisted of four half day training sessions (total 16 hours) spread over the first half year. As lifestyle education belonged already to the job of the general practice nurses, the size of the training was comparable to the study of Rubak in general practice that showed a positive effect of MI on general practitioners' professional behaviour[29]. Nurses attended these sessions in groups of 5 to 8 outside the practice. A professional trainer provided all training sessions. The program consisted of the theory of MI, group discussions, role playing in which nurses alternately played the role of patient, nurse or observer, and an individual assignment after the training to bring the MI theory in daily practice. The record keeping and instruction chart were offered to nurses during the last training session. They received an oral and written explanation of the record keeping. It was recommended to have regular telephone follow ups that would be monthly in the first half year and probably decrease afterwards. The research team called the nurses quarterly (three times) to inquire about the progress in

practicing MI, and offered a help desk that could be reached during daytime. At the request of the nurses an extra training session was planned after four months to discuss the barriers in practice and to receive feedback about their own video recording. The nurses in the control group were advised to give usual care.

Box 2. The several interventions of the comprehensive diabetes program

Training in motivational interviewing (4 half-days, spread equally over 6 months)

1. **Training** primary care nurses in the principles of **motivational interviewing (MI)** in order to encourage patients with diabetes to adhere to lifestyle guidelines. The following components were discussed:
   - *Building motivation for change: importance and confidence*
   - *Asking open questions, listening reflectively, affirming, summarizing, and eliciting change*
   - *Expressing empathy, developing discretion, rolling with resistance, and supporting self-efficacy.*

Structured diabetes care

2. Training in **agenda setting** to make consultations more structured and to draw up concrete appointments.
3. Tailoring a **diabetes protocol** to the local setting.
4. Introducing a **social map** for lifestyle change to primary care nurses. The map provides an overview of all available organizations and their treatment programmes to help patients choose, for example, the right sport school or physiotherapist.

Lifestyle counselling embedded in usual care

5. **Record keeping** of consultation data and changes in the behaviour of patients, conducted by primary care nurses.

Maintained motivational interviewing

Reminder

6. An **instruction chart** with counselling techniques, as a reminder for nurses to encourage maintenance of the MI techniques used to help patients change.

Follow-up

7. Recommendations for **regular telephone follow-ups** for diabetes patients, which are monthly in the first 6 months and then probably decrease.
8. A **help desk**: the research team will call the primary care nurse three times to inquire about their development of health counselling and nurses can call the research team for information.
9. A **follow-up meeting** to receive feedback about their own video recordings.

Measures and data collection

The nurses made video recordings of five type 2 diabetes consultations with different patients during the months February to May 2007 (baseline). The patients had to give consent for the recordings and its usage in the study. The recordings had to have clear sound. If video recordings failed, audio recordings were accepted. Nurses, who did not respond, were repeatedly reminded by e-mail and telephone until the program started. All nurses were asked to record again five videos of diabetes consultations after roughly a year (14 months) during the months April to September 2008. The recordings were rated with the Behaviour Change Counselling Index (BECCI) checklist[30] to evaluate the practice of the MI skills. Lane and colleagues developed the BECCI specifically to evaluate brief MI consultations. It consists of 11 items and uses a five-point rating scale (0–4) ranging from "not at all" to "a great extent". The checklist was completed with three global items from the Motivational Interviewing Treatment Integrity instrument[31] and ten specific MI items that were addressed in the training course. These 13 items were rated on identical five-point scales as used in the BECCI. The features of the consultations that is consultation time, the amount of nurse communication, and the amount of lifestyle discussion as well as the patients' readiness to change were identified by the judges during the rating of the videos. The judges assessed the patients' readiness to change, by means of a predetermined scoring list. In this scoring list was described how the judges had to assess the patients' readiness to change. It was a subjectively observation that could be expressed on a five-point rating scale (0–4) ranging from "not at all" to "a great extent". The nurses' demographic characteristics and data about their experiences as nurses or with MI were collected in self-reported questionnaires at baseline.

Rating consultations

The first author (RJ) trained two judges (CS and NV) to rate the recorded consultations. They examined the recordings twice, made notes, and gave their judgments. The judges were independent and were blinded for allocation of the nurses to the intervention or control group.

Ethical considerations

The Medical Ethics Committee of the Radboud University Nijmegen approved this study. Nurses received an invitation letter with information about the

study, the possibility of withdrawing at any time, and the guarantee of confidentiality. Consultations were only recorded after the patients were informed about the aim of the study and had given their permission.

Data analysis

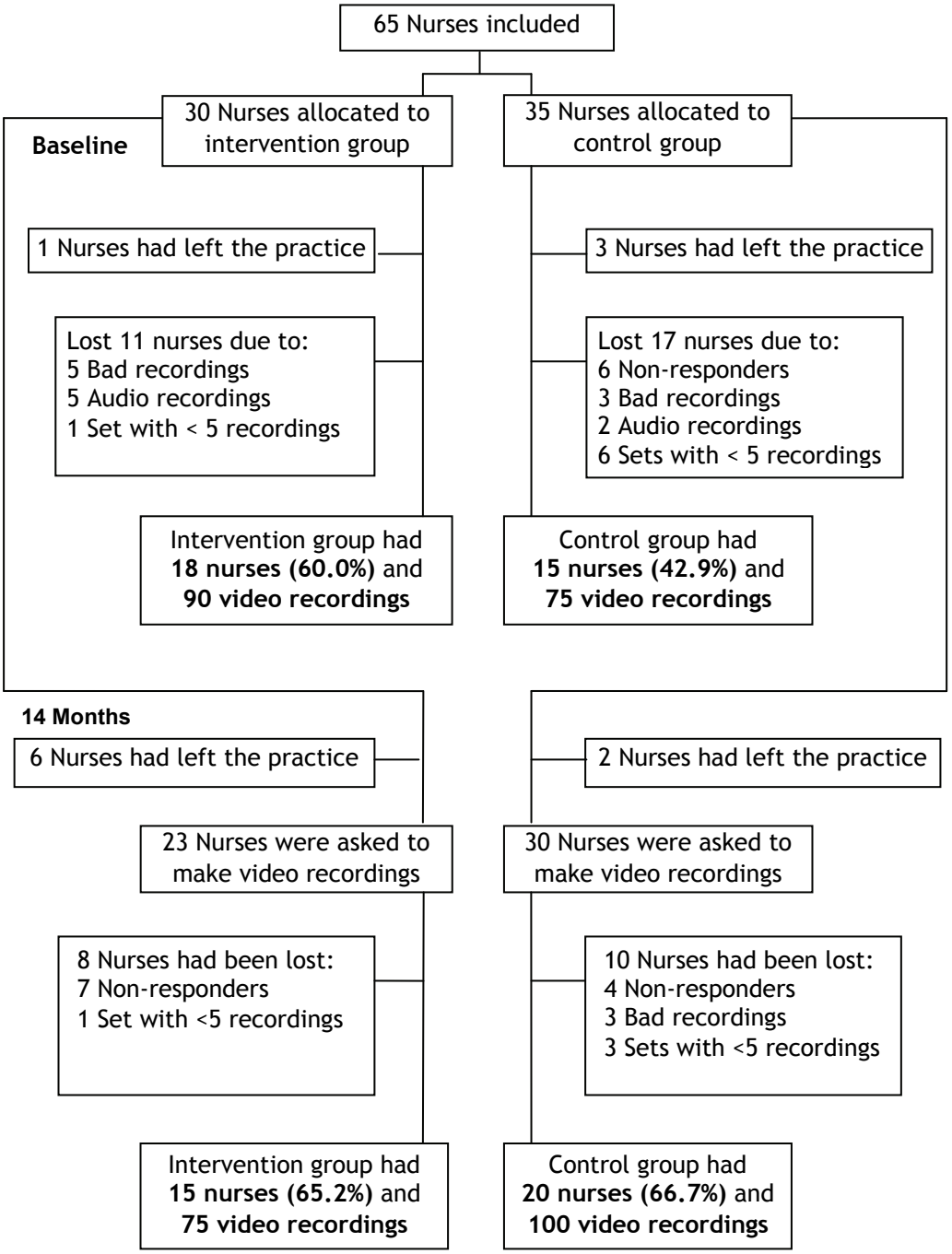
Means with ranges or percentages were used to describe the nurse characteristics. The intra-class correlation coefficient (ICC) was calculated to determine the agreement of the two judges. For the items on the BECCI checklist as well as the additional items about MI the Cronbach's alpha was used. The MI skills are expressed by means and standard deviations based on the items of the BECCI checklists and the additional items at baseline and at one-year follow-up. To compare the intervention group with usual care on the different MI skills a multilevel linear regression analysis (three levels: nurse, consultation, and measurement) was performed. Separate models were estimated for the BECCI list and the additional items; both models were adjusted for nurse characteristics that differed significantly between the intervention and usual care groups at baseline. Differences were considered significant if $p < 0.05$. To establish, overall, which consultation characteristics might influence the utilization of MI skills, the one-year follow-up data were analysed in a multilevel regression (top down procedure); again these analyses were performed separately for the BECCI items and the additional MI items. The least and non-significant components were deleted step by step, separately for both models. Intervention effects were examined in the most reduced models with a significance of 0.05 as the cut-off point. SPSS for Windows was used for the statistical analyses.

Results

Study population

Figure 1 presents the numbers of general practices and nurses in this trial. Sixty-five nurses participated in the study; 30 nurses were trained[28], while 35 nurses in the control group were invited to take the training course after the intervention. Sixty percent of the intervention group nurses and 43% of the control group nurses supplied five usable baseline video recordings; 65% of the intervention group nurses and 67% of the control group nurses supplied five recordings at one-year follow-up.

Figure 1. Flow diagram showing numbers of participants



The control group had significantly more experience as practice assistants than the intervention group (table 1). A practice assistant in the Netherlands is someone who assists a doctor and works predominantly as a receptionist and administrative assistant[32]. Since 1999, practice assistants can follow a 2 year training to become a primary care nurse. The non-responders did not differ significantly from the responders with regard to sex, age, background, experience as practice assistants, and experience with diabetes consultations.

Table 1. Nurses' characteristics at baseline

	Intervention group[a]	**Control group[a]**
Nurses	20	23
Percentage of male nurses	10.0	4.3
Mean age in years (range)	41.6 (27–57)	43.7 (31–57)
Percentage of nurses who were formerly practice assistants	45.0	60.9
Mean years of experience as a practice assistant (range) *	**4.4 (0–16)**	**9.7 (0–28)**
Mean years of experience with diabetes consultations (range)	3.6 (0–10)	4.1 (1–8)
Percentage of nurses who had training in motivational interviewing besides the MILD training	30.4	40.7
Percentage of nurses who engaged in other motivational interviewing activities besides the MILD training	43.5	40.7

*$p < 0.05$; [a] Nurses who participated at baseline and/or 14 months later; MILD, Motivational interviewing to change the lifestyle of patients with type 2 diabetes.

Improvement of MI skills

The audio recordings (n=35) were difficult to rate, because information was missing or more difficult to interpret. Therefore, the audio recordings were disregarded and only video recordings were allowed for the one-year follow-up. Table 2 shows that nurses only showed a significant improvement in 2 of the MI skills at one-year follow-up compared to baseline. The mean scores for most items were below point two on the 5-point scales. The BECCI checklist gave an ICC of 0.79 for the two judges and a Cronbach's alpha of 0.88 that can be judged as "good". A small, but significant, improvement in the intervention group versus the control group was seen for just one item: "nurse invites the patient to talk about behaviour change" (table 2). The ICC for the two judges on the 13 additional MI items was 0.67, and these items had Cronbach's alpha of 0.63 that can be judged as "moderately". There was a small, significant improvement in the intervention group compared to the control group in the score for "nurse assesses patients' confidence in changing their lifestyle" (table 2).

Table 2. Scores on the Behaviour Change Counselling Index checklist and additional questions

	Baseline		One-year follow-up		Effects			
Range 0 ('not at all') – 4 ('a great extent')	**Inter-vention**	**Control**	**Inter-vention**	**Control**	**Inter-vention**	**Control**	**Difference in change between groups**	***p* value**
Motivational interviewing: mean scores (s.d.) on the BECCI	1.53 (0.47)	1.49 (0.45)	1.63 (0.65)	1.42 (0.52)	0.07 (0.09)	-0.08 (0.09)	0.15 (0.12)	0.237
1. Nurse invites the patient to talk about behaviour change	1.43 (0.77)	1.67 (0.69)	1.50 (0.78)	1.36 (0.77)	0.13 (0.11)	**-0.26 (0.11)***	**0.39 (0.15)***	**0.009***
2. Nurse demonstrates sensitivity to talking about other issues	2.77 (0.68)	2.78 (0.65)	2.92 (0.64)	2.56 (0.62)	0.19 (0.13)	0.05 (0.13)	0.14 (0.18)	0.440
3. Nurse encourages patient to talk about current behaviour	2.00 (0.93)	1.93 (0.86)	1.89 (1.04)	1.72 (0.96)	-0.20 (0.14)	-0.21 (0.14)	0.01 (0.19)	0.941
4. Nurse encourages patient to talk about change	1.62 (0.92)	1.61 (0.85)	1.76 (1.07)	1.50 (0.82)	0.10 (0.14)	-0.09 (0.14)	0.19 (0.20)	0.343
5. Nurse asks questions to find out how patient thinks and feels about topic	0.93 (1.04)	0.85 (1.00)	1.37 (1.24)	0.85 (1.00)	**0.41 (0.18)***	-0.00 (0.18)	0.41 (0.25)	0.110
6. Nurse uses empathic listening statements when the patient talks about the topic	2.24 (0.64)	2.11 (0.61)	2.25 (0.95)	2.11 (0.71)	-0.01 (0.11)	0.02 (0.11)	-0.03 (0.15)	0.846
7. Nurse uses summaries to bring together what the patient says about the topic	0.20 (0.45)	0.16 (0.44)	0.46 (0.65)	0.24 (0.47)	**0.19 (0.07)***	0.11 (0.07)	0.08 (0.09)	0.395
8. Nurse acknowledges challenges about behaviour change that the patient faces	2.22 (0.80)	2.12 (0.72)	2.08 (0.95)	1.96 (1.10)	0.03 (0.13)	-0.07 (0.12)	0.10 (0.18)	0.562
9. When nurse provides information, she is sensitive to the patient's concerns and understanding	1.72 (0.60)	1.77 (0.94)	1.59(0.60)	1.40 (0.63)	-0.07 (0.08)	**-0.17 (0.08)***	0.10 (0.11)	0.378

	Baseline		One-year follow-up		Effects			
Range 0 ('not at all') – 4 ('a great extent')	**Inter-vention**	**Control**	**Inter-vention**	**Control**	**Inter-vention**	**Control**	**Difference in change between groups**	***p* value**
10. Nurse actively conveys respect for patient choice about behaviour change	1.82 (0.75)	1.93 (0.72)	1.82 (1.04)	1.85 (0.92)	0.03 (0.14)	-0.05 (0.13)	0.08 (0.19)	0.679
11. Nurse and patient exchange ideas about how the patient could change current behaviour	1.29 (0.98)	1.45 (1.05)	1.27 (1.15)	1.39 (1.12)	-0.07 (0.14)	-0.07 (0.14)	-0.00 (0.20)	0.984
Motivational interviewing: mean scores (s.d.) on additional questionnaire	1.21 (0.25)	1.16 (0.23)	1.42 (0.36)	1.24 (0.23)	**0.19 (0.05)***	0.08 (0.05)	0.11 (0.07)	0.133
1. Global score: empathy	2.16 (0.36)	2.05 (0.41)	2.37 (0.54)	2.20 (0.47)	**0.20 (0.08)***	0.15 (0.08)	0.05 (0.11)	0.667
2. Global score: spirit	1.92 (0.37)	1.94 (0.39)	2.04 (0.51)	1.91 (0.35)	0.09 (0.06)	-0.03 (0.06)	0.12 (0.08)	0.146
3. Global score: structure in consultation	2.86 (0.36)	2.89 (0.35)	2.93 (0.26)	2.93 (0.26)	0.05 (0.06)	0.06 (0.06)	0.01 (0.07)	0.902
4. Nurse applies agenda setting and gives structure to the consultation	1.06 (0.27)	1.13 (0.47)	1.11 (0.28)	1.17 (0.37)	0.05 (0.06)	0.05 (0.06)	-0.00 (0.08)	0.955
5. Nurse assesses patient's importance of changing their undesirable lifestyle	0.11 (0.36)	0.15 (0.41)	0.33 (0.61)	0.18 (0.45)	0.13 (0.09)	0.01 (0.09)	0.13 (0.13)	0.314
6. Nurse assesses patient's confidence in changing lifestyle	0.16 (0.42)	0.27 (0.51)	0.62 (0.78)	0.35 (0.67)	**0.33 (0.09)***	0.05 (0.09)	**0.28 (0.13)***	**0.037***
7. Nurse draws up concrete and feasible goals with the patient	0.69 (0.85)	0.73 (0.90)	1.11 (0.99)	0.92 (0.92)	**0.38 (0.14)***	0.19 (0.14)	0.19 (0.20)	0.360
8. Nurse rolls with resistance, is flexible, and avoids discussion	1.85 (0.80)	1.90 (0.88)	2.03 (0.93)	2.07 (0.72)	**0.26 (0.10)***	0.15 (0.10)	0.11 (0.14)	0.415
9. Nurse supports and reinforces the self-efficacy of the patient	0.56 (0.96)	0.40 (0.88)	1.11 (1.28)	0.64 (0.96)	**0.56 (0.15)***	0.24 (0.15)	0.32 (0.21)	0.126

	Baseline		One-year follow-up		Effects			
Range 0 ('not at all') – 4 ('a great extent')	**Inter-vention**	**Control**	**Inter-vention**	**Control**	**Inter-vention**	**Control**	**Difference in change between groups**	***p* value**
10. Nurse highlights and helps resolve discrepancy between present behaviour and important personal goals	0.00 (0.00)	0.05 (0.21)	0.14 (0.35)	0.09 (0.28)	**0.14 (0.04)***	0.04 (0.04)	0.10 (0.05)	0.054
11. Nurse asks open questions instead of closed questions as often as possible	1.71 (1.52)	1.30 (1.50)	1.55 (1.55)	1.21 (1.51)	-0.24 (0.22)	-0.08 (0.22)	-0.16 (0.32)	0.625
12. Nurse applies reflections	2.14 (0.35)	2.04 (0.36)	2.17 (0.41)	2.08 (0.35)	0.01 (0.05)	0.04 (0.05)	-0.04 (0.08)	0.636
13. Nurse is sitting behind the chair	0.49 (0.58)	0.31 (0.52)	0.94 (0.95)	0.40 (0.63)	**0.43 (0.17)***	0.10 (0.17)	0.33 (0.24)	0.177

*p < 0.05 was considered significant
a BECCI, Behaviour Change Counselling Index
The values were adjusted for experience as a practice assistant

Consultation characteristics

The mean duration of consultation differed significantly between intervention (21.8 minutes) and control group (17.6 minutes). Table 3 shows that nurses used significantly more MI skills measured by the BECCI if the consultation took more time (B-estimate= 0.13; s.d.= 0.05), and when more time was spent discussing lifestyle factors (B-estimate = 8.97; s.d.= 0.71). The time lifestyle discussed was also positively associated with the additional MI items (B-estimate= 4.28; s.d.= 0.53) as well as the patients readiness to change (B-estimate= 1.41; s.d.= 0.58).

Table 3. Regression between consultation characteristics and the extent to which nurses applied motivational interviewing

	Motivational interviewing BECCI			**Motivational interviewing additional questions**		
Consultations (*n* = 175)	*B-estimate*	*s.d.*	*p-value*	*B-estimate*	*s.d.*	*p-value*
Consultation time in minutes	0.13	0.05	0.011*	-	-	-
Amount of nurse talk during consultation	-	-	-	-	-	-
Time given to lifestyle during consultation	8.98	0.71	0.000*	4.28	0.53	0.000*
Patients' readiness to change	-	-	-	1.41	0.58	0.015*

*p < 0.05
BECCI; Behaviour Change Counselling Index

Discussion

The MI training embedded in a comprehensive program to improve routine diabetes care in general practice had a minimal impact upon lifestyle counseling practice of MI skills when assessed at one-year follow-up. The comparison of video consultations in a cluster randomized controlled trial showed that two of the 24 MI skills improved, that is "the invitation to talk about behavioural change" and "the assessment of patients' confidence to change". In general, it can be stated that nurses showed more MI skills if the consultations took more time and when more lifestyle issues were discussed. The observed patients' readiness to change was also positively related to the degree of MI skills expressed.

Strengths and limitations of the study

A strength of the study is the RCT design, and the number of videos that could be rated (n=340).

Clinical trials on MI in diabetes care seldom include a fidelity check of the actual use of MI skills[19,29,33]. Rubak et al. (2006) described that general practitioners changed their behaviour in daily practice after an MI course[29]. However, this study used self-reported data, which tend to be less reliable than objective measures such as observations[34]. Miller et al. (2004) assessed MI skills after training with audio taped samples that lack non-verbal information[35]. They argued that appropriate assessment of MI practice is necessary in studies on MI in order to explore the effects of true MI practice, and that direct monitoring of practice is the gold standard, since self-report of the MI practitioners are unreliable[35]. Such direct monitoring in this study was performed by means of tape recordings of counseling sessions.
Another strength of the study is the high agreement among the judges. The checklists used to rate MI skills (BECCI, and some additional questions) probably supported the rating process well. A possible limitation of the study is a bias due to the self-selection of the video recordings of the consultations. Nurses told us that it was very difficult to arrange a good camera setting. They often had to borrow a camera. Based on this feedback, it was assumed that being highly selective of taped consultations was not feasible. This endorses the results that the intervention had a minimal impact upon MI skill in routine diabetes care.

MI skills at one-year follow-up

It is difficult to compare the study results with other studies, because few studies measured the effect of training on nurses' MI skills in diabetes care and evaluated it in such detail with recordings of diabetes consultations. At one-year follow-up, it was demonstrated that the nurses improved minimally on their MI skills. This is in line with previous findings suggesting that MI skills are not easily applicable in daily practice[17,26]. Others, showed that health care practitioners who wished to learn MI were able to acquire MI skills up to at least beginning proficiency and transfer these skills to a real life clinical setting[14], but in this study it is not known whether the practitioners continued to use MI in routine practice after the study period. Miller et al. (2004) reported, based on audio tapes, that the intervention group showed greater gains in MI skills than the control group, but MI performance diminished without further training support[35]. This phenomenon could also have affected the presented study results.

Lacking lifestyle counselling skills

Nurses often state that skills for lifestyle counselling are lacking[36,37]. In many countries, such as the Netherlands, diabetes care is largely delegated to primary care nurses. Nurses are trained in a three to four years curriculum (middle or higher education) and afterwards they can specialize in primary care following a one or two years curriculum. In the curriculum, interviewing techniques are addressed but not specific to MI. Consequently, the nurses who participated were trained in MI, such as suggested by Rubak et al.[29], but they showed little change in MI skills when assessed at one-year follow-up. A review supported the idea that our number of MI training sessions was sufficient[38]. Other studies suggest that training alone is not enough for acquiring MI skills. Ongoing coaching/feedback, written material and supervision are also essential[14,16,17,39]. Continued support on the job seems to be needed[40] in which MI skills can be practiced and evaluated during daily routine over a longer period of time. Moreover, it is important that health care providers are supported by their supervisor and colleagues in performing MI[27].

Separate MI sessions

The association of time and time spent on lifestyle discussion with MI skills has been concluded by others as well[17] and it fits into the debate that separate MI sessions are successful[22,41]. In the Netherlands, nurses see patients with type 2 diabetes four times a year for 15 to 20 minutes. In these diabetes consultations glucose level, blood pressure, and weight must be measured, information about the effect of the medication is updated, the nurse attempts to educate the patient about diabetes and the relation of diabetes complications to diet, physical activity, and smoking behaviour. The nurses in the intervention group took on average 21.8 minutes consultation time which was 4 minutes more than in the control group. But, possible this time is not enough for performing successful lifestyle counselling. Making lifestyle counselling part of diabetes care seems to require more time that probably is easier to realize in a separate MI session.

Diabetes care and MI

MI was originally developed for substance abuse[10] which requires a single behavioural change. MI may be less effective for multiple behavioural changes

needed in a complex chronic illness such as diabetes mellitus. Although, some studies showed an effect of MI on diabetes care[9,19,21,22].
However, these studies seldom observed MI skills in practice. Therefore, it is unclear if the effect can be attributed to MI skills or to the intervention in general. Our comprehensive diabetes program, including the training, had no significant effect on HbA1c, blood pressure and cholesterol level nor on reported aspects of lifestyle or quality of life[42]. Since, the MI skills showed minimal improvement at one-year follow-up, the attribution problem cannot be solved yet. It is possible that more training is needed or that MI only can be effective in certain groups of people. A review showed that for type 1 diabetes psychological treatments could improve glycaemic controls, but only in children and adolescents[43]. More studies are needed that probably will sketch a nuanced picture.

Conclusion
The utilization of MI skills of primary care nurses showed minimal improvement after MI training embedded in a comprehensive program to improve routine diabetes care. It is unclear if the success of MI as such should be questioned, whether the technique is less appropriate in routine care for patients with more complex lifestyle conditions, or that nurses have problems with the acquisition and maintenance of MI skills in daily practice.

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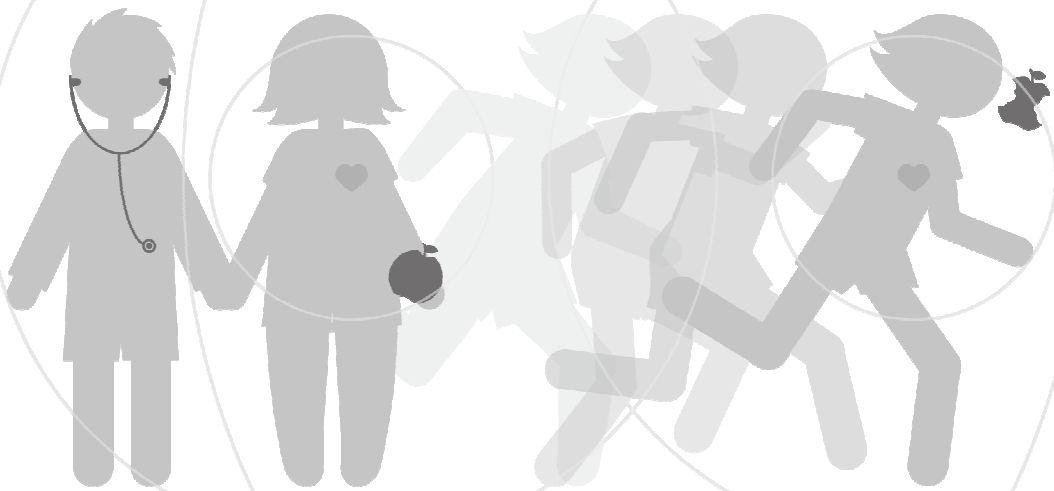
Chapter 7

General discussion



Introduction

This thesis fits into a growing body of research on improving care for patients with type 2 diabetes in which lifestyle counselling plays a crucial role. A comprehensive structured diabetes programme focussing on lifestyle counselling through motivational interviewing (MI) was developed to improve diabetes care. This programme was evaluated in a cluster randomised controlled trial (RCT) on the following outcomes: HbA1c and lifestyle behaviours such as diet and physical activity. In an in-depth process evaluation nurses' skills on MI were studied using video consultations. Prior to the main study the misperceptions of patients with type 2 diabetes on diet and physical activity were considered, as misperception is related to readiness to change. Furthermore, a qualitative study was performed to learn about the barriers for lifestyle change as perceived by nurses. Based on this information the structured diabetes programme, focussed on lifestyle counselling, was fine-tuned. In this chapter, the main findings of the studies are discussed, the methodological issues are reviewed and future research and implications for practice are discussed.

Misperceptions on diet and physical activity (chapter 2)

Key findings

- The proportion of patients with type 2 diabetes who misperceived their diet (fruit, vegetable, and fat) and physical activity behaviour was slightly larger than the proportion in the Dutch general population.
- Patients with type 2 diabetes often have more than one lifestyle problem, and these behaviours are all prone to misperceptions. Our study showed that misperceptions on different lifestyle behaviours were hardly related, except for the fruit and fat consumption. It is therefore possible for patients to accurately perceive one lifestyle behaviour, while misperceiving another.
- As misperception is related to readiness to change, we recommend reviewing actual lifestyle behaviours and discussing these with the patient in order to address possible misperceptions.

Many patients are not aware of their unhealthy lifestyle, and therefore often misperceive their own health-related behaviours. Diabetes patients misperceive their diet and physical activity behaviour somewhat more than the general population. The complexity of the disorder can be a possible explanation. Diabetes care requires patients to pay attention to various aspects such as

monitoring blood pressure, glucose, and medication, besides diet and physical activity[1]. Agenda setting can be a tool to prioritise these activities. This will make consultations more structured and it will lead to a more concrete action plan[2]. However, the weak clustering of misperceptions of different lifestyle behaviours makes lifestyle counselling for patients with diabetes even more complex, because the misperception of each lifestyle behaviour has to be explored separately in order to find the roots of the main problem. Since misperception is related to readiness to change[3-5], this problem cannot be ignored. To improve readiness to change, awareness of unhealthy lifestyle behaviours needs to be established. Once the necessity of changing lifestyle is clear, arrangements can be made on the specific goals that an individual patient aims to reach. The study in chapter 2 also showed that in prioritising goals in terms of readiness to change it is better to look at the confidence people have in reaching the goal, rather than at the perceived importance. Another Dutch study confirms this result[6], but other findings show that recognizing the importance of the behaviour change is also a strong predictor of change[7]. These inconsistencies might be attributed to the particular lifestyle behaviours that were studied or to a difference in measurement[6].

Nurse perceived barriers for lifestyle change (chapter 3)

Key findings

- Nurses generally believed that diabetes patients had limited knowledge of a healthy lifestyle, limited insight into their own behaviour, and a lack of motivation to modify their lifestyle or lack of discipline to maintain an improved lifestyle.
- Although nurses understand this problem, they felt that they lacked time and lifestyle counselling skills to handle the problem effectively.

In addition to other studies[8-10], we also concluded that nurses experienced barriers at the level of the patient in particular. Nurses were very willing to help patients with regard to lifestyle changes by providing them with lifestyle information/advice. They were also inclined to take over the responsibilities of the patient. However, these activities often resulted in resistance on the part of the patient, because the advice given was unsolicited and the responsibility was not shared with the patients. Besides, nurses tended to have false or too high expectations for lifestyle changes of their patients (jumping ahead of the

patient). Goals that had been set were often not attained, making nurses feel powerless[10]. Nurses reported a need to improve their own counselling skills[10,11] and to have sufficient time for lifestyle counselling[10,12,13].

Comprehensive diabetes programme (chapter 4, 5 and 6)

Key findings

- A possible successful programme on improving diabetes care may include different actions to support primary care nurses (see also box 1):
  a) training in lifestyle counselling based on MI[14];
  b) the introduction of tools for structuring diabetes care, such as training in agenda setting, a local diabetes protocol based on national guidelines[15], and a social map for lifestyle support;
  c) instruction on record keeping to integrate lifestyle counselling into general practice;
  d) introduction of tools to sustain improvements including an instruction chart (reminder)[16], regular telephone follow-ups with the target patients, a help desk that also inquires pro-actively about the progress of diabetes management, and a follow-up meeting for the nurses.
- However, a programme developed along all these lines had no effect on clinical parameters (neither process nor outcome indicators), lifestyle, quality of life, and readiness to change lifestyle.
- At one-year follow-up, it was demonstrated that the nurses improved only two of 24 MI skills, namely, "inviting patients with type 2 diabetes to talk about behaviour change" and "assessing patient's confidence in changing their lifestyle". Baseline results showed that improvement was possible, and nurses actively participated in the training programme.
- Consultation time, the time given to lifestyle counselling, and the patients' readiness to change were all positively related to nurses' MI usage.

Although our programme was based on elements which proved to be effective, such as structured diabetes management[16] and MI[17-19], it had no effect on patients' outcome measures and only small effects on nurses' outcome measures. Previous research showed that the use of MI can improve glucose control, dietary changes, weight, physical activity, motivation for lifestyle change, and adherence to diabetes guidelines for patients with type 2 diabetes[17-19]. Knowing that dietary advice and physical activity are associated

with a lower HbA1c[20], we expected our comprehensive diabetes programme to have an effect on HbA1c and lifestyle. However, recently more studies have questioned the effectiveness of MI in terms of clinical outcomes, lifestyle, quality of life and self-efficacy for patients with type 1 and 2 diabetes or in cardiovascular risk management in routine care in general practice[21-24]. Because the training in MI was a main component in our programme, we will particularly discuss MI here. Possible explanations for the lack of effect will be discussed at nurse level, patient level, and practice level.

Box 1. The several interventions of the comprehensive diabetes programme

Training in motivational interviewing (4 half-days, spread equally over 6 months)

1. **Training** primary care nurses in the principles of **motivational interviewing (MI)** in order to encourage patients with diabetes to adhere to lifestyle guidelines. The following components were discussed:
   - *Building motivation for change: importance and confidence*
   - *Asking open questions, listening reflectively, affirming, summarizing, and eliciting change*
   - *Expressing empathy, developing discretion, rolling with resistance, and supporting self-efficacy.*

Structured diabetes care

2. Training in **agenda setting** to make consultations more structured and to draw up concrete appointments.
3. Tailoring a **diabetes protocol** to the local setting.
4. Introducing a **social map** for lifestyle change to primary care nurses. The map provides an overview of all available organizations and their treatment programmes to help patients choose, for example, the right sport school or physiotherapist.

Lifestyle counselling embedded in usual care

5. **Record keeping** of consultation data and changes in the behaviour of patients, conducted by primary care nurses.

Maintained motivational interviewing

Reminder

6. An **instruction chart** with counselling techniques, as a reminder for nurses to encourage maintenance of the MI techniques used to help patients change.

Follow-up

7. Recommendations for **regular telephone follow-ups** for diabetes patients, which are monthly in the first 6 months and then probably decrease.
8. A **help desk**: the research team will call the primary care nurse three times to inquire about their development of health counselling and nurses can call the research team for information.
9. A **follow-up meeting** to receive feedback about their own video recordings.

Nurse level

Before the comprehensive diabetes programme was introduced nurses stated that they lacked skills for lifestyle counselling[9,10,13,25,26]. One year after the programme nurses still expressed the feeling that they lacked appropriate skills for lifestyle counselling. On a scale from 1 (not complete) to 10 (complete), nurses gave a 6 for the extent in which they perceived to have sufficient skills to apply MI in practice, and a 6.2 for the extent they were sufficiently equipped to MI in daily practice, see table 1. Studying the video consultations, the feeling of lacking skills was confirmed. We rated the application of 24 MI skills based on five consultation recordings per nurse at baseline and after a one-year follow-up. MI skills by nurses were hardly present both before and after the programme[27]. Therefore, the maintenance of the MI skills one year after the training program was minimal. Heinrich et al.[28] also concluded that MI skills were difficult to implement in daily diabetes care. Furthermore, a recent study in the USA concluded that nurses felt a need for additional training to master behaviour change counselling (BCC) skills, after a 1-day training in BCC with 2 follow-up telephone calls[29].

Nurses face the difficult task to adhere to diabetes guidelines, and to motivate patients to lifestyle change. Possibly, adherence to the biomedical parameters of diabetes guidelines distracts nurses from applying their MI skills[30]. On the other hand, the level of experience of nurses seems to facilitate intervention success[31]. Other explanations for the lack of effect can probably be found in the difficulty of mastering MI skills, and in the lack of opportunities to embed MI skills in routine practice. Studies have shown that MI skills can be taught to practice nurses[32-34], but research on the long-term effects is not available. Perhaps one year after the programme MI skills have eroded somewhat. During routine consultations, nurses had to measure blood pressure, HbA1c and weight. Lifestyle counselling is an extra task that needs time and resources for it to become successful[35]. Van Eijk-Hustings et al.[36] recommended a phased training in MI for nurses, with sufficient time and support by colleagues in daily practice. Such a programme could be helpful to embed MI skills in routine practice. But even if time and resources are available, nurses need to break with their counselling routines to make truly practising MI possible.

Table 1. Nurses' experience of the comprehensive programme for improving diabetes care

Questions about nurses' experience of the MI training, follow-up period, and working with MI in daily practice	Mean (range)*
1. How do you experience the 4 MI training sessions?	8.04 (5-10)
2. How do you experience the follow-up meeting?	8.10 (5-10)
3. How do you experience the help desk function?	7.77 (6-10)
4. Did you invest time in learning MI, beside the training and follow-up meeting?	5.59 (2-8)
5. How much time did you invest in MI last year?	5.48 (2-9)
6. How difficult is it to learn MI?	5.13 (2-8)
7. How much motivation do you have to work with MI?	7.26 (3-9)
8. Have you performed MI in practice last year?	6.30 (2-9)
9. How do you experience working with MI?	7.30 (4-9)
10. To what extent do you have sufficient skills to apply MI in practice?	5.98 (3-9)
11. To what extent are you sufficiently equipped to MI in daily practice?	6.15 (3-8)
12. To what extent are you sure about continue working with MI?	6.90 (4-8)
13. Looking back, would you participate in the MILD project again?	7.22 (2-10)
14. Do you think the MILD project would be useful to other nurses?	7.83 (4-10)

* Scale: 1-10. 1=very negative (question 1, 2, 3, 9), not much (question 4, 5, 7, 8), very difficult (question 6), not complete (question 10, 11), or very uncertain (question 12, 13, 14);
10=very positive (question 1, 2, 3, 9), very much (question 4, 5, 7, 8), very easy (question 6), complete (question 10, 11), or very certain (question 12, 13, 14).

Patient level

Lifestyle change is not only a challenge for nurses, but also for patients. Successful behavioural change can most likely be accomplished by promoting patients' awareness of personal risk behaviour[37] and with it their readiness to change[38]. These aspects were addressed in our programme. A review in 2008 of the clinical effectiveness of diabetes education programmes showed a mixed picture of effective elements of the various programmes[16,35]. Diabetes educational programmes are often multifaceted, providing information as well as management skills around diet, exercise, self-monitoring and medication use[35]. Most of these education programmes are based on cognitive behaviour change as expressed in the Theory of Planned Behavior (TPB)[39], the Social Cognitive Theory[40], the Health Belief Model (HBM)[41], The Transtheoretical Model (TTM)[42], the Precaution Adoption Process Model (PAPM)[43], Attitude–Social Influence–Self-efficacy model (ASE-model)[39], The Integrated Change model (The I-Change Model)[44], and the Health Action Process Approach model (HAPA)[45]. Another way to approach lifestyle change is to change the environment by reducing diet temptations, and by convincing people to take part in active behaviour. However, the availability of partner support also seems to facilitate intervention success[31]. Apart from our perceptions, the environment is a huge

driving force of our lifestyle habits[46,47]. Therefore, solely focussing on rational behaviour may be less effective than redesigning the environment.
During the design of our study, our study population appeared to be very suited to the programme, since most patients with type 2 diabetes are supposed to be able to improve their diabetes by changing their lifestyle behaviour. It is possible that we slightly overestimated this readiness to change. Especially for patients with type 2 diabetes, it may be difficult to change their lifestyle, because it is a complex disorder that requires patients to pay attention to various aspects of his/her lifestyle[1]. Adherence to a multifaceted treatment regimen is an enormous challenge[48], in which lifestyle change is just one element. Besides, our study population consisted of elderly patients (mean 64 years), with the majority of them having suffered from diabetes for a prolonged time period (7.7 years). This may have had an impact on their effort to change habits. However, the number of years that people suffer from diabetes is probably not a limiting factor. The DESMOND study with newly diagnosed type 2 diabetes in primary care also showed no differences in biomedical or lifestyle outcomes at three years[49].

Practice level
Assuming that lifestyle counselling performed by primary care nurses can support diabetes patients, an effective programme also needs a facilitating organisation for the practice nurses. Our findings indicated that more time is necessary, especially more time for lifestyle counselling during consultations with patients. In the Netherlands, a quarterly check-up appointment usually takes 15 to 20 minutes. During this time, the glucose level, blood pressure, and weight is measured, information about the effect of the medication is updated, and at the same time the nurse should try to inform the patient about diabetes and the relation of diabetes complications to diet, physical activity, and smoking behaviour. It is therefore not surprising that nurses lack time to perform lifestyle counselling during these routine consultations. Other studies also indicated that lifestyle counselling needs time[50] and resources to become a success[35]. Time was often seen as a major barrier in implementation projects and should be well arranged at the practice level in order to make improvements possible.

Methodological considerations

A variety of research methods was used to answer the research questions of this thesis. The study on misperception was a cross-sectional survey (chapter 2), the study on nurses' barriers in lifestyle changing was based on qualitative semi-structured interviews (chapter 3), the implementation of lifestyle changes was evaluated by a cluster randomised controlled trial (RCT) on clinical parameters (process or outcome indicators), lifestyle, quality of life, and readiness to change lifestyle (chapter 5) as well as on the nurses' performance of MI skills (chapter 6).

Cross-sectional survey

The misperception of patients with type 2 diabetes on diet and physical activity was explored by using a cross-sectional survey (chapter 2). In this study, we collected data using patient questionnaires. A weakness of the study was the relatively low response rate on the questionnaires, a problem that also occurred in similar Dutch studies[51,52]. Another limitation was the self-reported character of the patient questionnaires. This may have led to socially desirable answers. Even so, the questionnaires were validated instruments that are widely used for behavioural studies on lifestyle behaviours.

Qualitative semi-structured interviews

Qualitative semi-structured interviews were performed to learn about the barriers for lifestyle change, as perceived by nurses (chapter 3). Based on this information, our structured diabetes programme with a focus on lifestyle counselling was fine-tuned. The interviews were audio-recorded, transcribed verbatim, and two researchers scored and classified the comments independently according to a predetermined framework until data saturation was achieved. Collecting and analysing these data was time consuming, but in our opinion the method yielded valuable data to be used in the design of our intervention.

Cluster randomised controlled trial

The effect evaluation was conducted in a cluster randomised controlled trial (RCT) in a real practice setting (chapter 5). The design of a cluster RCT for pragmatic implementation studies where the level of intervention (nurses were trained) is different than the level of analysis (patient) is optimal from the

methodological perspective. The strength of the design was the involvement of many practices with relatively few patients instead of a few practices with relatively many patients[53,54]. Incorporating more practices in the study increases the chance of successful implementation at practice level, while decreasing cluster contamination. Also more information becomes available on the conditions necessary for implementing our strategy in a large group of practices.

Video study

Nurses' skills on MI were studied by using video consultations (chapter 6). Most implementation studies of MI in diabetes care used self-reported data of MI performance, which tend to be less reliable than objective measures, such as audio-taped or video recordings[55]. The benefit of video recordings compared to audio-taped recordings was that nonverbal information can also be rated. The strength of the study was the large number of video recordings in our study: 340 recordings in total, with at least five consultations per nurse. Another strength is the high agreement among the raters, who used a short structured checklist on MI skills. A possible limitation of the study is a bias due to the self-selection of the video recordings of five successive consultations.

Different data resources

Different measures for collecting data were used. At nurse level: questionnaires, interviews and video recordings. At patient level: patient medical records, questionnaires, diaries for recording physical activity, and personality activity meters (PAM). The questionnaires were validated instruments that are widely used for behavioural studies on lifestyle behaviours. However, due to its self-administrative character the questionnaires may have led to socially desirable answers. Collecting and analysing the data of the interviews and video recordings was very time consuming, but the methods yielded valuable data to help in designing our intervention and to assess nurses' MI skills in diabetes care, respectively. Data from patient medical records helped us in gaining insight into the diabetes check-ups. The medical record is a powerful tool that allows the health care provider to track the patients' medical history and identify problems or patterns that may help determine the course of health care. However, the quality of the medical records is not always optimal, given the completeness of data, validity of diagnosis, etc. A combination of subjective and objective reporting was chosen to gain insight into exercise

routines. We used the personal activity meter (PAM) with a diary for recording physical activity for seven days. In general, we can conclude that the different methods for evaluating the intervention and the different measures for collecting data were appropriate for this study[56].

Implications for further research

Misperception on diet and physical activity

Few studies examined the misperception and its relation to readiness to change of patients with type 2 diabetes so far. When the origins of misperception are known, a targeted intervention to prevent or reduce misperception can be invented. This may improve patients' readiness to change lifestyle. Therefore, we recommend to do more research in the area of misperception.

Nurse perceived barriers for lifestyle change

Many studies investigated barriers for lifestyle change and recommended interventions to prevent these barriers. However, interventions often did not attain the desired effect in lifestyle change for patients with type 2 diabetes. We recommend gaining more insight into determinants of effective interventions on lifestyle change for patients with type 2 diabetes at the level of the nurse, the patient, as well as the practice. In addition, the role patients have in the performance of MI skills by nurses should be further investigated[30].

Comprehensive diabetes programme

Since the evidence of the effect of a relatively brief MI training in general practice seems to be inconclusive, more research is necessary regarding the effectiveness of MI-based interventions for people with a complex chronic condition. A systematic review addressing training in MI was published in 2009[57]. However, the authors did not draw conclusions about the effectiveness of different types of training methods and about the optimal training time, due to the limited information on the training activities. This is partly because training activities are often only minimally described. But more importantly, training methods did not vary enough to draw conclusions on the effectiveness of different methods. The methods most often for training were through didactic instruction and experimental exercises[28]. In contrast to our study, the majority of courses contained a workshop format without further feedback. Feedback and follow-up coaching are however essential[16,58]. Therefore, more research

about detailed MI training methods is needed to draw conclusions on optimal MI training methods.

The development of an effective training programme should be linked to a discussion about the best setting. The question is whether general practice is the best setting or whether we need special clinics. Such special clinics can be community-based or organised by primary care. The benefit of lifestyle counselling in general practice is that as a rule patients with type 2 diabetes visit the primary care nurse four times a year. However, it could be more effective when other health care providers, such as a general practitioner, physiotherapist and a dietician, also contribute to lifestyle counselling by bringing in their own expertise. This means that health care providers need to work in a team with the patient at its centre, in which case the primary care nurse can function as the case manager of patients with type 2 diabetes.

Next, it could be worthwhile to search for support by peers. Social support seems to be effective to contribute to successful behaviour change in patients[37]. In the EUROACTION study, patients' partners and other family members were actively involved in changing lifestyle[59]. It was shown that this family intervention was successful, because the patients who underwent the biggest changes had partners undergoing similar changes[59].

Another element of effective improvement is a better inclusion of the patients' perspective in this process. Adherence to a multifaceted treatment regimen is a challenge for patients with type 2 diabetes, in which patients seem more likely to adhere to their medication regimens than to work on nutrition and exercise changes[48]. Perhaps we need to invest more time in the dialogue between patient and physician?

Another direction for research is a more fundamental one. The assumption in this thesis was that health care professionals are able to motivate patients. This is quite a dominant line of reasoning in changing lifestyle behaviour. As a consequence, interventions are built around motivating both health care professionals and patients. However, perhaps environmental factors influence lifestyle more effectively than motivation factors. To achieve a more integrated approach to the promotions of a healthy lifestyle, all health care professionals and health care organisations, as well as schools, governmental and other public organisations need to communicate the same message and facilitate a healthy lifestyle. Besides unequivocal communication, it is important to make a healthy lifestyle the easiest lifestyle to achieve. This means that we should take health

into account when constructing our physical environment. For example, more people will use the stairs rather than the lift if the stairs have been centrally located in a building, and fewer people will buy unhealthy food when it has been displayed on the lowest shelves in supermarkets. Changing the environment in a way that the diabetes patient is seduced to change lifestyle is a research field that needs to be explored in more detail as well.

Practice implications

According to current theories on behavioural change nurses should start by removing the first barrier, that is the lack of awareness[3-5]. Counsellors should check with a questionnaire on self-report whether patients have indeed reached the third stage of awareness; patients should become aware that their own behaviour is unhealthy. This is a precondition for readiness to change health behaviour. Once the necessity of changing lifestyle is clear, arrangements can be made on the goals that the patient wants to achieve. Agenda setting can be a tool to prioritise these activities. This will make consultations more structured and will lead to a more concrete and shared action plan[6].

At nurse level practical tools for agenda setting as well as lifestyle counselling have to become part of daily practice. A training programme can guide the nurse in using these tools, but it probably should be extended with an on the job learning programme[60], the basics of which should be incorporated into the curriculum for primary care nurses.

Organisational changes are also needed to support effective lifestyle counselling. Currently, feedback on clinical outcomes of diabetes care is often given, though not on counselling skills[61]. Supervision can improve the quality of diabetes care and, additionally, peer support can help in acquiring new skills. A more flexible organisation of care in which the length, frequency and content of consultations may vary depending on patients' needs would offer nurses the opportunity to tailor health care[50]. Another possibility is to organise separate MI-surgeries with sufficient time for lifestyle counselling techniques and for discussing lifestyle behaviour with different disciplines; these proved to be more successful than MI integrated in routine diabetes consultations[62].

Final conclusion

We conclude that our comprehensive structured diabetes programme focussing on lifestyle counselling by MI did not improve diabetes care outcomes in primary care. There were no effects on clinical parameters, such as HbA1c, blood pressure, cholesterol, and BMI (neither process nor outcome indicators), lifestyle (consumption of alcohol, fat, vegetables, and fat), quality of life, readiness to change lifestyle, while hardly any of the primary care nurses' MI skills were improved after 14 months. Overall, performing MI skills during consultation may increase if there is more time available, more discussion of lifestyle to take place, and patients show more readiness to change. The question is whether the success of MI to change unhealthy behaviour should be doubted, or perhaps the technique is less suitable for patients with a complex chronic disease, such as diabetes mellitus.

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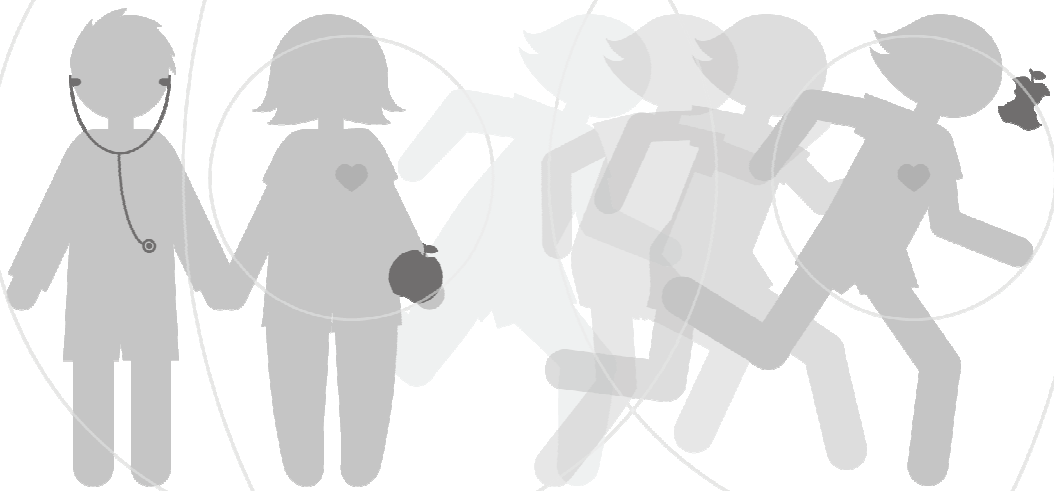
Summary



This thesis focusses on the development and evaluation of a comprehensive structured programme focussing on lifestyle counselling aimed at improving diabetes care. Health care professionals' adherence to type 2 diabetes recommendations on diet and physical activity is considered to be of utmost relevance, due to its impact on diabetes clinical outcomes. Even so, relatively little attention is given to lifestyle counselling by health care professionals during diabetes consultations. A programme aimed at structured diabetes care, including reminders and feedback for professionals and a clear role for lifestyle counselling, may have the potential to improve diabetes care. Yet no studies are available that evaluated such a comprehensive approach.

Chapter 1 describes the objective and research questions of the present thesis. The purpose was to gain insight into:

- the misperceptions about lifestyle among patients with type 2 diabetes and their effects on readiness to change (chapter 2);
- nurses' barriers to lifestyle counselling for patients with type 2 diabetes (chapter 3);
- development of a comprehensive structured programme to improve diabetes care and a study design (chapter 4)
- the effect of this programme on clinical parameters, lifestyle, as well as quality of life and patients' readiness to change lifestyle (chapter 5); and
- the effect of this programme on nurses' skills on MI one year after the training (chapter 6).

Chapter 2 describes a cross-sectional survey on misperceptions about lifestyle among patients with type 2 diabetes and their effects on readiness to change. Many patients are not aware of their unhealthy lifestyle and consequently misperceive their own behaviours. Five hundred twenty-one participants (55.4%) completed the validated questionnaires. Misperception existed for physical activity (41.5%) and diet; consumption of fruit (40.1%), consumption of vegetables (69.2%), and consumption of fat (21.6%). Misperception significantly affected readiness to change the relevant lifestyle, except in the case of fruit consumption. The degree of misperception varied between the different lifestyle behaviours and was somewhat larger compared to the general Dutch

population. In conclusion, patients with type 2 diabetes misperceive their lifestyle behaviours, which could hinder lifestyle changes.

In **Chapter 3** we present a study with semi-structured qualitative interviews to examine barriers that nurses encounter in lifestyle counselling to patients with type 2 diabetes at nurse level, patient level, and practice level. Twelve interviews took place with nurses in Dutch general practices involved in diabetes care. The nurses particularly identified barriers at the level of the patient; for instance, patients had limited knowledge of what constituted a healthy lifestyle and limited insight into their own behaviour, and they lacked the motivation to modify lifestyles or the discipline to maintain an improved lifestyle. Furthermore, nurses reported lack of counselling skills and insufficient time as barriers in effective lifestyle counselling. In general, a traditional health education approach with simple advice is still dominant in primary care in case of patients with type 2 diabetes, whereas a more counselling-based approach seems to be more effective. An implementation strategy such as motivational interviewing (MI) can probably help to promote skills in lifestyle behavioural change.

Chapter 4 describes the study protocol of the MILD study (Motivational Interviewing by primary care nurses to change Lifestyle for patients with type 2 Diabetes). This study is intended to improve diabetes care in accordance with the national guidelines on diabetes care and healthy lifestyle. To reach this goal a programme was developed in which primary care nurses received four training sessions in lifestyle counselling based on MI. Other components of the programme were the introduction of tools for structuring diabetes care, such as training in agenda setting, a local diabetes protocol based on the national guidelines, a social map, instruction on record keeping, and support to sustain improvements by introducing an instruction chart (reminder), regular telephone follow-ups with the target patients, a help desk that also inquired pro-actively about the progress of diabetes management, and a follow-up meeting for the nurses. In this chapter the research question of the trial has been formulated, as well as the associated measurements, the timing of measurements and the data analysis. An effect evaluation, a process evaluation as well as an economic evaluation formed part of the main study. The intervention of the MILD study was investigated in a cluster, randomised controlled trial (RCT) involving

general practices in the south-eastern part of the Netherlands. The control arm was encouraged to maintain usual care. The effect measures concerned the care process, metabolic parameters (HbA1c, blood pressure, lipids, and BMI), lifestyle (diet, physical activity, smoking, and alcohol), quality of life, and patients' readiness to change behaviour. The measurements took place at baseline and after 14 months. According to a power analysis we planned to recruit 70 practices and to include 700 patients with type 2 diabetes, an HbA1c concentration above 7%, and a body mass index (BMI) above 25 kg/m^2.

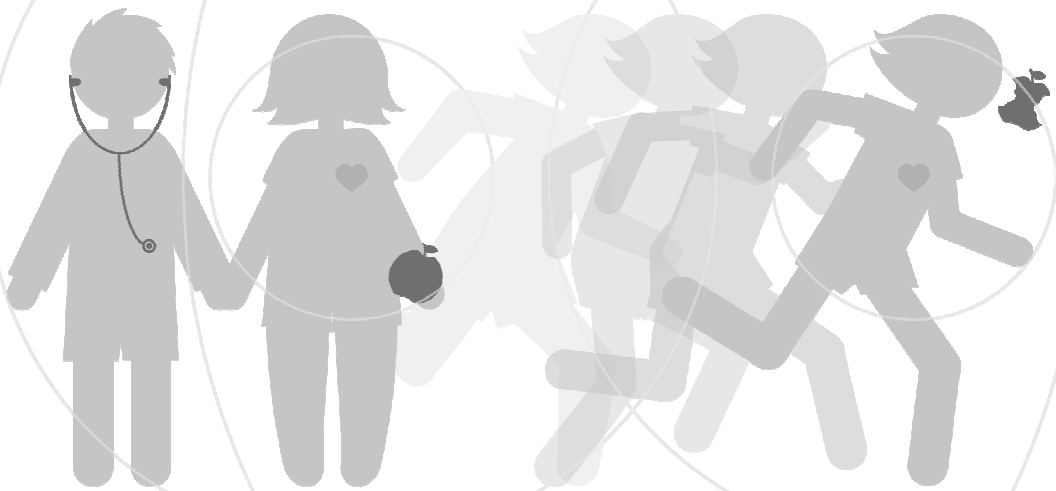
In **Chapter 5** we report on the effectiveness of the comprehensive programme to improve diabetes in general practice with a focus on lifestyle counselling. Primary care nurses in 58 general practices and their 940 type 2 diabetes patients were included. Despite active nurse participation in the training sessions, the programme was no more effective than the usual care after 14 months, as shown by HbA1c levels, fat intake, consumption of vegetables, consumption of fruit, and physical activity, or any of the other measures of clinical parameters, patient's readiness to change or quality of life. We concluded that our programme, which integrated lifestyle counselling based on MI principles into structured diabetes care, did not alter HbA1c or the lifestyle related to diet and physical activity. We thus question the impact of MI in terms of its ability to improve routine diabetes care in general practice.

In **chapter 6** we present a cluster randomised trial to assess nurses' skills in MI one year after the training embedded in a comprehensive programme to improve routine diabetes care in general practice. In fifty-eight general practices recordings of diabetes consultations were made, both in the usual care group (n=35 nurses) and the intervention group (n=30 nurses). The diabetes consultations were independently rated on applying 24 MI skills by two raters, both at baseline and after 14 months. Ratings were based on five consultation recordings per nurse. Trained nurses improved on two of 24 MI skills, namely, "inviting the patient to talk about behaviour change", and "assessing patient's confidence in changing their lifestyle". Consultation time, patients' readiness to change their lifestyle, and the degree to which lifestyle was discussed during the consultation proved to be supportive in applying MI skills. We concluded that the maintenance of the MI skills one year after the training was minimal.

The actual use of MI skills during consultation requires an extension of the consultation time.

The main findings of this thesis have been summarised and discussed in **chapter 7**. This thesis contributes to the body of knowledge on improving actual health care for patients with type 2 diabetes. We concluded that our programme focussing on lifestyle counselling by MI did not improve diabetes care or outcomes in primary care. There were no effects on clinical parameters, such as HbA1c, blood pressure, cholesterol, and BMI (neither process nor outcome indicators), lifestyle (consumption of alcohol, fat, vegetables, and fruit), quality of life, or readiness to change lifestyle. Moreover, the use of MI skills of the nurses was hardly improved, despite training. The factors consultation time, patients' readiness to change their lifestyle, and the degree to which lifestyle was discussed during the consultation were positive related to nurses' MI usage. MI is probably unsuitable for routine diabetes care. Perhaps separate MI sessions are needed to create sufficient time for lifestyle counselling techniques and for discussing lifestyle behaviour. As MI formed only one part of our programme, it can also be concluded that simply more structure and sending reminders and feedback is no longer enough to improve diabetes care. Future research should focus on the implementation of MI in routine diabetes care, with more time for the counsellor. However, it would also be interesting to study the environment of patients with type 2 diabetes.

Samenvatting



Dit proefschrift beschrijft de ontwikkeling en evaluatie van een uitgebreid gestructureerd diabetesprogramma met de focus op leefstijlcounseling en heeft als doel de diabeteszorg te verbeteren. Het volgen van diabetes type 2 richtlijnen ten aanzien van voeding en beweging wordt door zorgprofessionals als uitermate relevant beschouwd vanwege de invloed ervan op klinische diabetes uitkomstmaten. Desondanks besteden ze weinig aandacht aan leefstijlcounseling tijdens diabetesconsulten. Een programma, gebaseerd op gestructureerde diabeteszorg met herinneringen en feedback voor zorgprofessionals en een prominente rol voor leefstijlcounseling, heeft de potentie om de diabeteszorg te verbeteren. Er zijn nog geen studies beschikbaar die zo'n uitgebreid programma evalueren.

Hoofdstuk 1 beschrijft het doel en de onderzoeksvragen van dit proefschrift. Deze betreffen:

- inzicht krijgen in de mispercepties van mensen met diabetes type 2 over hun leefstijl en welk verband dit heeft met de bereidheid om hun leefstijl te veranderen (hoofdstuk 2);
- een exploratie van de barrières die praktijkondersteuners ondervinden gedurende leefstijladvisering aan mensen met diabetes type 2 (hoofdstuk 3);
- het ontwikkelen van een uitgebreid gestructureerd programma met als doel de diabeteszorg te verbeteren en het ontwikkelen van een studieopzet (hoofdstuk 4);
- het meten van het effect van dit programma op klinische parameters, leefstijl, kwaliteit van leven en de bereidheid van patiënten om hun leefstijl te veranderen (hoofdstuk 5); en
- het meten van het effect van dit programma op de vaardigheden van praktijkondersteuners in motiverende gespreksvoering één jaar na de training (hoofdstuk 6).

Hoofdstuk 2 beschrijft een studie met betrekking tot de mispercepties van mensen met diabetes type 2 over hun leefstijl en welk verband dit heeft met de bereidheid om hun leefstijl te veranderen. Veel mensen zijn zich niet bewust van hun ongezonde leefstijl; zij schatten hun gedrag verkeerd in. Vijfhonderd eenentwintig deelnemers (55,4%) vulden de gevalideerde vragenlijsten in. Misperceptie bestond over beweging (41,5%) en over voeding; fruitconsumptie (40,1%), groenteconsumptie (69,2%), en vetconsumptie (21,6%). Misperceptie

heeft significant invloed op de bereidheid om de leefstijl te veranderen, met uitzondering van fruitconsumptie. De mate van misperceptie varieert tussen de verschillende leefstijlen en was iets sterker bij mensen met diabetes type 2 dan bij de Nederlandse bevolking als geheel. Concluderend kan gezegd worden dat mensen met diabetes type 2 hun leefstijl niet juist waarnemen, wat een barrière kan zijn voor leefstijlveranderingen.

In **hoofdstuk 3** presenteren wij een kwalitatief semigestructureerde studie met als doel te onderzoeken welke barrières praktijkondersteuners tegenkomen tijdens leefstijladvisering bij mensen met diabetes type 2, waarbij een onderscheid wordt gemaakt tussen problemen die de praktijkondersteuner bij zichzelf ziet, bij de patiënt en in de organisatie van de praktijk. Twaalf interviews vonden plaats met praktijkondersteuners uit Nederlandse huisartspraktijken, die betrokken waren bij de diabeteszorg. De praktijkondersteuners ondervonden de meeste barrières op het niveau van de patiënt. Gesteld werd dat patiënten beperkte kennis hebben van gezonde leefstijl en een beperkt inzicht hebben in hun eigen gedrag. Daarnaast ontbreekt het patiënten aan motivatie om hun leefstijl aan te passen of de discipline om een verbeterde leefstijl te behouden. Praktijkondersteuners gaven verder aan dat zij zelf vaardigheden en tijd missen om effectieve leefstijladvisering uit te oefenen. De praktijkondersteuners geven wel vaak advies, maar van leefstijlcounseling is niet of nauwelijks sprake. Een implementatiestrategie gebaseerd op motiverende gespreksvoering kan mogelijk de communicatievaardigheden bevorderen die relevant zijn bij leefstijlveranderingen.

Hoofdstuk 4 beschrijft het onderzoeksprotocol van de MILD-studie (Motiverende Interviewing door praktijkondersteuners om Leefstijlverandering bij Diabetes type 2 te bewerkstelligen). Deze studie is bedoeld om de diabeteszorg te verbeteren volgens de nationale richtlijnen betreffende diabeteszorg en gezonde leefstijl. Om dit doel te bereiken is een programma ontwikkeld waarin praktijkondersteuners deelnamen aan vier trainingssessies over leefstijlcounseling gebaseerd op motiverende gespreksvoering, oftewel “motivational interviewing” (MI). Andere componenten van het programma waren de introductie van handvaten om de diabeteszorg te structureren, zoals training in het opstellen van de agenda, een lokaal diabetesprotocol gebaseerd

op nationale richtlijnen, en een sociale kaart; en instructies over het bijhouden van het medisch dossier met informatie over leefstijlcounseling. Om de interventie in te bedden - ook voor de langere termijn - is een instructiekaart (ter herinnering) geïntroduceerd, een helpdesk die ook proactief informeert naar de voortgang van het diabetesmanagement en een vervolgbijeenkomst voor praktijkondersteuners. Aan de praktijkondersteuners is meegegeven dat regelmatige telefoongesprekken met patiënten kunnen bijdragen aan het goed uitvoeren van MI. In dit hoofdstuk wordt ook de onderzoeksvraag van de trial geformuleerd, evenals de daarbij behorende metingen, het tijdspad en het analyseplan. Een effect-, een proces- en een economische evaluatie waren onderdeel van de hoofdstudie. De interventie van de MILD-studie is onderzocht in een geclusterd gerandomiseerde gecontroleerde studie (RCT) met huisartspraktijken uit het zuiden en oosten van Nederland. Praktijkondersteuners uit de controlegroep bleven alleen de reguliere diabeteszorg leveren ('usual care'). De effectvariabelen betroffen het zorgproces, metabolische parameters (HbA1c, bloeddruk, lipiden en BMI), leefstijl (voeding, beweging, roken en alcohol), kwaliteit van leven en de bereidheid van patiënten om hun gedrag te veranderen. Voor deze variabelen is een nulmeting uitgevoerd, waarna ze na 14 maanden nogmaals werden gemeten. Op basis van een poweranalyse was de planning om 70 praktijken te werven en om 700 mensen met diabetes type 2, een HbA1c concentratie boven de 7% en een body mass index (BMI) boven de 25 kg/m^2 te rekruteren.

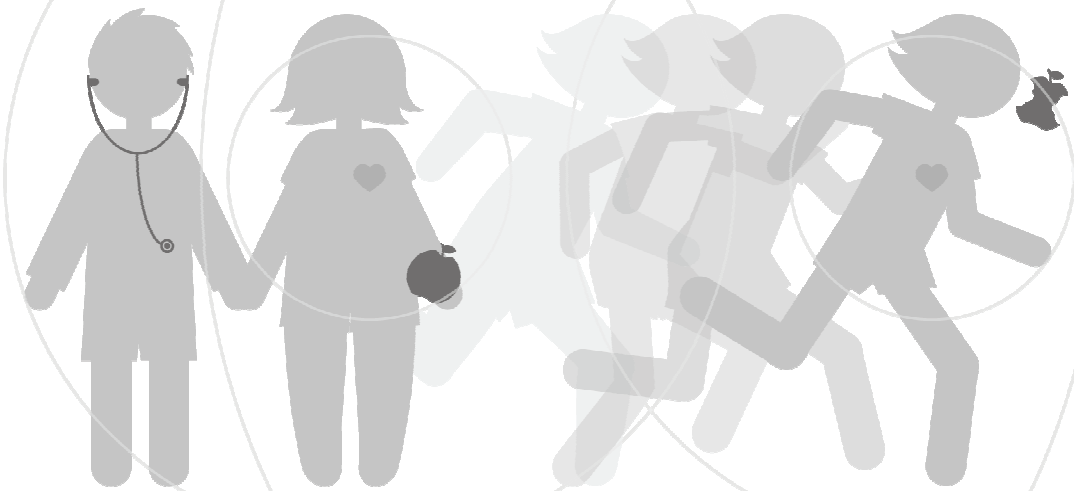
In **hoofdstuk 5** rapporteren we over de effectiviteit van het uitgebreide diabetesprogramma met de focus op leefstijlcounseling in huisartspraktijken. Praktijkondersteuners in 58 huisartspraktijken en 940 mensen met diabetes type 2 werden geïncludeerd. Ondanks de actieve deelname van praktijkondersteuners in de trainingsessies was het programma na 14 maanden niet effectiever dan de gebruikelijke zorg. Dit bleek uit de HbA1c-waarden, vetinname, consumptie van groenten en fruit en de mate van beweging, maar ook uit de andere metingen, zoals klinische parameters, bereidheid van patiënten om te veranderen of kwaliteit van leven. Wij concluderen dat ons programma, dat leefstijlcounseling gebaseerd op motiverende gespreksvoering in gestructureerde diabeteszorg integreert, niet effectief was op de onderzochte maten. Daarom zetten wij vraagtekens bij de invloed van MI om routine diabeteszorg in huisartspraktijken te verbeteren.

Hoofdstuk 6 beschrijft een geclusterd gerandomiseerd onderzoek om de MI vaardigheden van praktijkondersteuners na één jaar te beoordelen. In 58 huisartsenpraktijken zijn opnames gemaakt van diabetesconsulten in zowel de controlegroep (n=35 praktijkondersteuners) als de interventiegroep (n= 30 praktijkondersteuners). De diabetesconsulten zijn onafhankelijk beoordeeld door twee personen op het toepassen van 24 MI-technieken, bij aanvang van de studie en na 14 maanden. Er werden per praktijkondersteuner opnames gemaakt van vijf diabetesconsulten. Getrainde praktijkondersteuners verbeterden twee van de 24 motiverende gesprekstechnieken, namelijk "patiënten uitnodigen om over gedragsverandering te praten" en "het beoordelen van het vertrouwen dat een patiënt heeft om zijn of haar leefstijl te veranderen". Consulttijd, de bereidheid van een patiënt om zijn of haar leefstijl te veranderen en de mate waarin leefstijl wordt bediscussieerd tijdens een consult zijn van belang voor het toepassen van motiverende gespreksvoering. We concludeerden dat het behoud van motiverende gespreksvoering door praktijkondersteuners één jaar na training minimaal was. Het huidige gebruik van motiverende gespreksvoering tijdens consulten vereist een uitbreiding van de consulttijd.

De belangrijkste bevindingen van dit proefschrift worden in **hoofdstuk 7** samengevat en bediscussieerd. Dit proefschrift draagt bij aan de wetenschappelijke kennis op het gebied van de gezondheidszorg voor mensen met diabetes type 2. Wij concluderen dat het uitgebreide gestructureerde diabetesprogramma met de focus op leefstijlcounseling door motiverende gespreksvoering (MI) de diabeteszorg in de eerste lijn niet heeft verbeterd. Er zijn geen effecten opgetreden bij de klinische parameters, zoals de HbA1c, bloeddruk, cholesterol, BMI (niet op de procesindicator noch op de uitkomstindicator), leefstijl (alcohol-, vet-, groente-, en fruitconsumptie), kwaliteit van leven en bereidheid om de leefstijl te veranderen. Ondanks het uitgebreide trainingsprogramma, bleken de praktijkondersteuners nauwelijks vaardigheden op het gebied van MI toe te passen. De factoren consulttijd, de bereidheid van een patiënt om zijn of haar leefstijl te veranderen en de mate waarin leefstijl wordt bediscussieerd tijdens een consult, waren positief gerelateerd aan het gebruik van MI door praktijkondersteuners. MI is waarschijnlijk ongeschikt voor de diabeteszorg, zoals deze nu is ingericht in de eerstelijn. Wellicht kan met aparte MI sessies meer tijd gecreëerd worden voor

leefstijlcounseling. Aangezien MI een onderdeel van ons programma was, kan ook geconcludeerd worden dat meer structuur en het ontvangen van herinneringen en feedback eveneens geen verbetering teweeggebracht heeft in de diabeteszorg. Verder onderzoek zou zich kunnen richten op een goede inbedding van MI in de reguliere zorg, met meer tijd voor de zorgprofessionals. Maar ook de omgeving van mensen met diabetes type 2 zou een onderwerp voor verder onderzoek kunnen zijn.

Dankwoord



Het afronden van dit proefschrift is een mooi moment om terug te blikken op de vele mensen die een bijdrage hebben geleverd aan de totstandkoming van dit proefschrift. Zonder hun steun, begeleiding, kennis en vertrouwen was dit proefschrift er niet geweest. Ik wil daarom graag van de gelegenheid gebruik maken om een aantal mensen hiervoor hartelijk te danken.

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Curriculum Vitae

Renate Jansink werd geboren op 8 april 1982 in Haaksbergen. Tot haar 8ste levensjaar groeide zij op in Haaksbergen, daarna verhuisde zij met haar ouders en zus naar Lonneker. Zij behaalde in 2000 haar VWO diploma aan het Twents Carmel Lyceum te Oldenzaal. Daarna begon zij aan de opleiding Biomedische Wetenschappen aan de Radboud Universiteit Nijmegen. In 2005 studeerde zij af met het hoofdvak 'Toxicologie', de bijvakken 'Arbeid, Milieu en Gezondheid', 'Voeding en Gezondheid' en een Communicatie profiel.

Na afronding van haar studie kwam zij in dienst bij TNO Kwaliteit van Leven in Zeist, waar zij voor enkele maanden haar afstudeerstage voortzette. In februari 2006 begon zij op de afdeling IQ Healthcare aan de Radboud Universiteit Nijmegen als junior onderzoeker aan het promotietraject 'Improving diabetes care. Nurse-led lifestyle counselling in primary care'. Eind 2009 heeft Renate ervoor gekozen haar promotieonderzoek te combineren met de functie als adviseur bij Stichting OOGG te Dodewaard. Bij Stichting OOGG heeft zij de doelgroep praktijkondersteuners in haar portefeuille en houdt zij zich momenteel hoofdzakelijk bezig met de onderwerpen ouderenzorg en geestelijke gezondheidszorg (GGZ). In dit kader is zij als projectleider betrokken geweest bij het ontwikkelen van een ouderenloket in Bennekom en begeleidt zij momenteel de Regionale Organisatie Huisartsen Gelderse Vallei bij het versterken van de samenwerking in de eerstelijns GGZ. Eind 2012 heeft Renate vijf maanden, ter onderbreking van de werkzaamheden bij Stichting OOGG, voor de BV Chronische Zorg Gelders Rivierenland in Ochten gewerkt, waar zij zich o.a. bezig hield met de ketenzorg diabetes en cardiovasculair risicomanagement (CVRM). Sinds enkele jaren woont Renate samen met Mattijs Mudde in Capelle aan den IJssel.